

**Investigation into the factors contributing to malpractice litigation
in nursing practice
within the private healthcare sector of Gauteng.**

AMY WILLIAMS

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for the degree of Master of Nursing Science
in the Faculty of Medicine and Health Sciences
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Supervisor: Prof E.L. Stellenberg

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ABSTRACT

INTRODUCTION

The number of medical negligence claims in South Africa has increased rapidly throughout the past decades, affecting both the public and private sectors.

RATIONALE

Patients are at the receiving end of negligent care provided by healthcare professional workers placing them in a vulnerable and life-threatening position.

RESEARCH PROBLEM

Factors leading to malpractice litigation in nursing practice within the private sector in South Africa are unknown, thus a scientific investigation was required.

RESEARCH QUESTION

“What are the factors that contribute to malpractice litigation in nursing practice within the private healthcare sector of Gauteng?”

RESEARCH AIM

To investigate factors that contributed to malpractice litigation within the private healthcare sector in Gauteng.

RESEARCH OBJECTIVES

The objectives for the study included:

- To complete an audit of the nursing process documents of a trial bundle
- Categorising the adverse events according to principle type leading to malpractice litigation that involved nursing practitioners.
- Identifying the factors contributing to the adverse events that have led to malpractice litigation, involving nursing practitioners.
- Identifying the other members of the multi-disciplinary health team that played a role in the adverse event that has resulted in malpractice litigation
- Assessing the severity of the adverse event that has led to malpractice litigation within the private healthcare setting

RESEARCH METHODOLOGY

Research design

A quantitative retrospective descriptive audit research design was applied.

Population and sampling

Convenience sampling was applied to select 41 malpractice litigation cases which occurred in the private healthcare sector of Gauteng over a period of six years.

Inclusion criteria

Malpractice litigation cases involving the private hospitals in Gauteng during 2011-2016.

Exclusion criteria

Any malpractice litigation case that has been used in the pilot study as well as any cases that might have received much media attention.

Data instrument and data collection

The researcher collected all the data using a validated audit instrument based on the objectives.

Reliability

The reliability of the audit instrument was tested by applying the test-retest method.

Validity

Content validity

Content of the audit instrument was based on the objectives, guided by the conceptual theoretical framework, literature and confirmed by experts that all elements to be measured were covered.

Face validity

The co-investigators of the main study, experts in quality assurance and the bio-statistician agreed that the instrument was valid.

Data analysis

The data were analysed by using the Statistical Package for the Social Sciences (SPSS) version 23 which enabled the researcher to categorise into principle type and to identify factors contributing to adverse events in nursing practice which lead to malpractice litigation.

ETHICAL CONSIDERATIONS

Ethical approval was sought prior to the study from the following organisations:

- Health Research Ethics Committee (Stellenbosch University, S16/10/222)
- Permission from law firms specialising in malpractice litigation in health care

RESULTS

This study revealed that most adverse events were severe (46.3%) of which 7.3% of the patients died.

Furthermore, it was identified that in 75.6% of the adverse events, clinical manifestations were not responded to.

CONCLUSION

It has been highlighted that the clinical management of the patient is a major problem as well as the adherence to the policies and protocols.

OPSOMMING

INLEIDING

Die getal van mediese nalatigheid eise in Suid-Afrika het vinnig oor die dekades verhoog en beïnvloed beide die openbare en private sektore.

RASIONAAL

Pasiënte is die ontvangers punt van nalatige mediese sorg wat deur professionele gesondheidsorgwerkers verskaf word, wat hulle in 'n kwesbare en lewensgevaarlike posisie plaas.

NAVORSING PROBLEEM

Faktore wat lei tot wanpraktyk litigasie in verpleegpraktyk binne die privaatsektor in Suid-Afrika is onbekend, dus was 'n wetenskaplike ondersoek nodig.

NAVORSING VRAAG

"Wat is die faktore wat bydra tot wanpraktyk litigasie in verpleegpraktyk binne die private gesondheidsorg sektor van Gauteng?"

NAVORSING DOEL

Om die faktore wat bygedra het tot wanpraktyk litigasie binne die private gesondheidsorg sektor in Gauteng te ondersoek.

NAVORSING DOELWITTE

Die doelwitte vir die studie het ingesluit:

- Voltooi 'n oudit van die verpleegprosesdokumente van 'n verhoor bondel•

Kategoriseer die nadelige gebeurtenisse volgens beginseltipe waarin verpleegpraktisyns betrokke was wat tot wanpraktyk litigasie gelei het.

- Identifiseer die faktore wat aanleiding tot nadelige gebeurtenisse gegee het wat tot wanpraktyk litigasie gelei het, waarby verpleegpraktisyns betrokke was.

- Identifiseer van die ander lede van die multi-dissiplinêre gesondheidspan wat 'n rol gespeel het in die nadelige gebeurtenis wat tot wanpraktyk litigasie gelei het.

- Beraam die erns van die nadelige gebeurtenis wat gelei het tot wanpraktyk litigasie binn die privaat gesondheidsorg sektor.

NAVORSINGSMETODIEK

Navorsing ontwerp

'n Kwantitatiewe, terugwerkende beskrywende oudit navorsingontwerp is aangewend.

Populasies en steekproef

Gerieflikheids steekproefneming is toegepas om 41 wanpraktyklitigasie gevalle te kies wat in die private gesondheidsorg sektor van Gauteng oor 'n tydperk van ses jaar plaas gevind het.

Insluiting kriteria

Wanpraktyk litigasie gevalle waarby die privaat hospitale in Gauteng gedurende 2011-2016 betrokke was.

Uitsluiting kriteria

Enige wanpraktyk litigasie saak wat in die loodsstudie gebruik is, sowel as enige gevalle wat dalk baie media-aandag ontvang het.

Data instrument en data versameling

Die navorser het met behulp van 'n geldige instrument, gebaseer op die doelwitte data versamel

Betroubaarheid

Die betroubaarheid van die oudit instrument is getoets deur die toepassing van die toets-hertoets metode.

Geldigheid

Inhoud geldigheid

Die inhoud van die oudit instrument is op die doelwitte gebaseer, gelei deur die konsepsuele teoretiese raamwerk en literatuur, en deur kundiges bevestig dat alle elemente vir meting ingesluit is.

Aangesig geldigheid

Die mede-navorsers van die hoofstudie, kundiges in gehalteversekering en die biostatistiekus het ingestem dat die instrument geldig was.

Data analise

Die data is met behulp van die Statistiese Pakket vir Sosiale Wetenskappe (SPSS) ontleed, wat die navorser instaat gestel het om die beginseltipe te kategoriseer en die faktore wat bydra tot die nadelige gebeurtenisse wat in verpleeg praktyk tot litigasie gelei het te, identifiseer.

ETIESE OORWEGINGS

Etiese goedkeuring is verleen voor die aanvangs van die studie van die volgende organisasies:

- Navorsing Gesondheid Etiese Komitee (Universiteit Stellenbosch, S16/10/222)
- Toestemming van wetgewende maatskappye wat in wanpraktylitigasie in gesondheidsorg spesialisee

RESULTATE

Hierdie studie het aan die lig gebring dat meeste (46.3%) nadelige gebeurtenisse ernstig was waarvan 7.3% van die pasiënte gesterf het.

Verder, is geïdentifiseer dat in 75.6% van die nadelige gebeurtenisse, kliniese manifestasies. nie op gerespondeer was nie

GEVOLGTREKKING

Dit is uitgelig dat die kliniese hantering van die pasiënt, sowel as die nakoming van die beleid en protokolle groot problem is.

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TABLE OF CONTENTS

CHAPTER 1.....	1
FOUNDATION OF THE STUDY	1
1.1 Introduction	1
1.2 Rationale	1
1.3 Significance of the problem	4
1.4 Research problem.....	5
1.5 Research question	5
1.6 Research aim.....	5
1.7 Research objectives.....	5
1.8 Conceptual framework	6
1.9 Research methodology	6
1.9.1 Research design.....	6
1.9.2 Study setting.....	7
1.9.3 Population and sampling.....	7
1.9.4 Audit instrument.....	7
1.9.5 Pilot Study	7
1.9.6 Reliability and Validity	7
1.9.6.1 Reliability	7
1.9.6.2 Validity	7
1.9.7 Data collection	8
1.9.8 Data analysis	8
1.10 Ethical considerations	8
1.11 Operational definitions	9
1.12 Duration of the study.....	10
1.13 Chapter outline	10
1.14 Summary	11
1.15 Conclusion	11
CHAPTER 2 LITERATURE REVIEW	12
2.1 Introduction	12
2.2 Patient safety	12
2.3 Adverse event.....	13
2.3.1 Errors in information.....	14

2.3.2	Errors in acquisition of knowledge.....	15
2.3.3	Errors in perception	15
2.3.4	Errors in matching.....	15
2.3.5	Errors in knowledge stored as schemata	15
2.3.6	Errors in knowledge stored as rules	15
2.3.7	Skills-based errors - slips and lapses.....	16
2.3.8	Errors in choice of rule	16
2.3.9	Technical errors	16
2.3.10	Deliberative errors	16
2.5	Professional negligence	18
2.5.1	Duty of care	19
2.5.2	Breach of duty.....	19
2.5.3	Causation	20
2.6	Damages	20
2.7	Safety assessment code categories.....	21
2.8	Vicarious liability	22
2.9	Legislation	23
2.9.1	The South African Constitution (Act 106 of 1996)	23
2.9.2	The National Health Act	23
2.9.3	South African Nursing Council	24
2.9.3.1	Regulation 767 of 1 October 2014: Acts and omissions	24
2.9.3.2	Regulation 786 of 15 October 2013: Scope of practice	25
2.9.3.3	Unprofessional conduct	26
2.9.3.4	The Nursing Process	27
2.10	Factors contributing to adverse events.....	29
2.10.1	Shortage of staff	29
2.10.2	Poor monitoring	32
2.10.3	Lack of training	33
2.10.4	Lack of adherence to policies.....	34
2.10.5	Professional ethics.....	34
2.10.6	National budget and procurement.....	35
2.10.7	Just culture	35
2.10.8	Attitude of nurses.....	36
2.10.9	Adverse event reporting.....	36
2.10.10	Media influence on healthcare	37
2.11	Summary	38

2.12	Conclusion	38
CHAPTER 3 RESEARCH METHODOLOGY		39
3.1	Introduction	39
3.2	Research objectives.....	39
3.3	Study setting	39
3.4	Research design	40
3.5	Population and sampling	40
3.5.1	Inclusion criteria	41
3.5.2	Exclusion criteria.....	41
3.6	Instrumentation	42
3.7	Pilot study	43
3.8	Reliability and validity	43
3.8.1	Reliability	43
3.8.2	Validity	44
3.8.2.1	Content validity	44
3.8.2.2	Face validity	44
3.9	Data collection	45
3.10	Data analysis	46
3.11	Summary	46
3.12	Conclusion	46
CHAPTER 4 DATA ANALYSIS, INTERPRETATION AND DISCUSSION		47
4.1	Introduction	47
4.2	Data analysis	47
4.3	Section A: The litigation	47
4.3.1	Question 1: How was the court case presented?	47
4.3.2	Question 2: If presented in court, indicate which High Court.	48
4.3.3	Question 3: If settled out of court, indicate the amount for which the case has been settled. (quantum to be paid).....	48
4.4.	Section B: Demographic data of the patient	48
4.4.1	Question 5: Age	48
4.4.2	Question 6: Gender	49
4.4.3	Question 7: Marital status	49
4.4.4	Question 8: Dependants	49
4.4.5	Question 9: Any disability on admission	50
4.4.6	Question 10: Indicate whether the patient had any of the following social habits	51

4.4.7	Question 11: Any underlying medical conditions on admission	51
4.4.8	Question 12: Employment at the time of admission	52
4.5.9	Question 13: Type of employment upon admission.....	52
4.5	Section C: Hospitalization	52
4.5.1 audit	Question 14: Indicate whether the nursing ward notes are available to	53
4.5.2	Question 15: Indicate the reason for admission	53
4.5.3	Question 16: Indicate the type of discipline the patient was admitted to prior to the adverse event.	54
4.5.4	Question 17: Indicate the type of ward or unit to which the patient was admitted to before the adverse event.	54
4.5.5	Question 18: Indicate the status of the initial assessment of the patient, including the foetus where applicable.....	55
4.6.7	Questions 19: Indicate the status of the care plan of the patient.	55
4.6.8	Question 20: Indicate whether the care plan was implemented.....	56
4.6.9	Question 21: Indicate whether special care plans were required.....	56
4.6.10	Question 22: Indicate the status of the special care plan of the patient ..	57
4.6.11	Question 23: Indicate whether the special care plan was implemented..	57
4.6.9 monitored	Question 24: Indicate whether any of the following vital signs were	58
4.6.10 pre-adverse event	Questions 25: Indicate whether the following diagnostic tests were done	64
4.6.11	Questions 26: Were the results of the tests interpreted?	64
4.6.12	Question 27: Were the results reported to the doctor?	65
4.6.13: Question 28:	Indicate whether any action was taken based on the results.....	65
4.6.14 surgery.	Question 29: Indicate the status of the pre-operative assessment for	66
4.6.15	Question 30: Indicate whether the treatment/ technique/ management as prescribed was given	66
4.6.16 the patient?	Question 31: Do the patient's "progress report" reflect the following about	67
4.6.17	Question 32: If the patient was discharged, indicate whether specific patient education was given.	67
4.7	Section D: Operation room.....	67
4.7.1	Questions 33: Indicate, where applicable, whether the following protocols in the operating room were adhered to:.....	68
4.8	Section E: Adverse event(s).....	68
4.8.1 occurred.	Question 34: Indicate the environment where the adverse event(s)	68

4.8.2	Question 35: Describe the adverse event(s)	69
4.8.3	Question 36: Indicate the patient outcome(s) as a result of the adverse event.	72
4.8.4	Question 37: Healthcare profession(s) or non-healthcare professional responsible for adverse event.	72
4.8.5	Question 38: Indicate the category or categories of nurses involved in the adverse event.	73
4.9	Section F: Principle incident type, severity of adverse event and factors contributing to the adverse event	74
4.9.1	Question 39: Indicate the adverse event by Principle Incident Type.....	74
4.9.2	Question 40: Indicate the severity of the adverse event according to the Safety Assessment Code Matrix (SAC).....	74
4.9.3	Question 41: Indicate the factors that have contributed to the adverse event.	75
4.10	Summary	75
4.11	Conclusion	76
CHAPTER 5 DISCUSSIONS, CONCLUSIONS AND RECOMMENDATIONS.....		77
5.1	Introduction	77
5.2	Objectives of the study.....	77
5.2.1.	To complete an audit of the nursing process.....	77
5.2.1.1	Assessment	77
5.2.1.2	Diagnosis and care plans.....	78
5.2.1.3	Implementation of care plans	78
5.2.3.4	Evaluation of the patient	78
5.2.2	Categorising the adverse events according to principle type which involved nursing practitioners that have led to malpractice litigation.....	80
5.2.3	Identifying the factors contributing to the adverse events involving nursing practitioners that have led to malpractice litigation.	81
5.2.4	Identifying the other members of the multi-disciplinary health team that played a role in the adverse event that has resulted in malpractice litigation	82
5.2.5	Assessing the severity of the adverse event that has led to malpractice litigation	82
5.3	RECOMMENDATIONS.....	82
5.3.1	Training courses in clinical management for continuous professional development	83
5.3.2	Supervision	83
5.3.4	Procurement and budgeting.....	84
5.3.5	Address the shortage of nursing practitioners	84
5.3.6	Addressing behavioural problems and attitudes within the workplace	84

5.3.7	Adverse event reporting	85
5.4	Limitations	85
5.5	Conclusion	86
	List of references	87
Appendix 1:	Instrumentation tool.....	93
Appendix 2:	Ethical approval	89
	Approved with Stipulations.....	89
Appendix 3:	Language editing certificate	92

LIST OF TABLES

Table 4.1: Age	48
Table 4.2: Dependants	50
Table 4.3: Social habits	51
Table 4.4: Type of employment upon admission	52
Table 4.5: Type of discipline the patient was admitted to prior to the adverse event	54
Table 4.6: Tests done pre-adverse event	64
Table 4.7: Reflection of patient's progress report	67
Table 4.8: Operating room protocols	68
Table 4.9: Environment where adverse event occurred.....	68
Table 4.10: Factors that has contributed to the adverse event	75

LIST OF FIGURES

Figure 4.1: Gender	49
Figure 4.2: Marital status.....	49
Figure 4.3: Disability on admission.....	50
Figure 4.4: Underlying medical condition on admission.....	51
Figure 4.5: Employment at time of admission.....	52
Figure 4.6: Nursing ward notes available to audit.....	53
Figure 4.8: Type of ward to which the patient was admitted before the adverse event	54
Figure 4. 9: Status of the initial assessment	55
Figure 4.10: Status of the care plan	55
Figure 4.11: Implementation of the care plan	56
Figure 4.12 Special care plans required.....	56
Figure 4.13: Status of special care plan	57
Figure 4.14: Implementation of special care plan	57
Figure 4.15: Blood pressure monitoring	58
Figure 4.16: Pulse Monitoring	58
Figure 4.17: Foot pulses monitoring	59
Figure 4.18: Foetal monitoring	59
Figure 4.19: Respiration monitoring	60
Figure 4.20: Intake and output monitoring	60
Figure 4.21: Weight monitoring	61
Figure 4.22: Neurological observations	61
Figure 4.23: Post-spinal surgery observations	62
Figure 4.24: Mental status monitoring	62
Figure 4.25: Continuous ECG monitoring.....	63
Figure 4.26: Continuous oxygen monitoring	63
Figure 4.27: Interpretation of diagnostic test results	64
Figure 4.28: Diagnostic test results reported to the doctor	65
Figure 4.29: Action taken based on the results.....	65
Figure 4.30: Pre-operative assessment done.....	66
Figure 4.31: Management was given as prescribed	66
Figure 4.32: Patient outcome as a result of the adverse event	72
Figure 4.33: Health profession(s) responsible for the adverse event.....	73
Figure 4.34: Indicate the categories of nurses involved in the adverse event	73
Figure 4.35: Adverse event by Principle Incident type	74
Figure 4.36: Adverse event according to the SAC Matrix	75

CHAPTER 1

FOUNDATION OF THE STUDY

1.1 INTRODUCTION

According to the South African National Health Act 61 of 2003, the right to health care is fundamental to the mental and physical well-being of every individual. The South African Constitution (Act 106 of 1996) provides three sections for the right to health care, namely:

- Access to healthcare services including emergency services and reproductive health
- Basic health care for children
- Medical services for prisoners and detained persons

The Council for Health Service Accreditation of South Africa (COHSASA, 2017:np) reported that for the year 2005, an average of 10% of in-visits resulted in a form of unintended harm, yet fifty percent of these in-visits resulted in healthcare errors found to be preventable.

South Africa is experiencing an increase in malpractice litigation as patients are becoming increasingly aware of their rights in an already overburdened healthcare system with limited resources (Pepper & Slabbert, 2011: 29).

The number of medical negligence claims in South Africa has increased rapidly throughout the years, affecting both the public and private sectors. There are various factors contributing to medical negligence claims and research is imperative.

1.2 RATIONALE

Patients are at the receiving end of negligent care provided by healthcare professionals placing them in a vulnerable and life-threatening position. Babies born with brain damage after medical mismanagement during labour and an infant turning blind after misdiagnosis at birth, are examples of medical negligence that contribute to malpractice claims costing provincial health departments millions of rand (Child, 2014:np).

The National Minister of Health of South Africa, Aaron Motsoaledi has requested an investigation into the increasing number of medical negligence cases in order to limit payouts and avoid the health department's bankruptcy (Child, 2014:np). Furthermore, the Health Professions Council of South Africa (HPCSA) has received 2 403 complaints between the period of April 2011 and March 2012 relating to claims of misdiagnosis, refusal to treat patients

and practising outside the scope of practice (Malherbe, 2013:83-8). Investigation into the factors leading to the malpractice litigation is of utmost importance. If the South African healthcare system cannot provide safe and effective services, the result will be that the recipients of the healthcare, as well as the economy will become negatively affected.

The Gauteng department of health faced claims regarding negligence amounting to R1.28-billion for the financial year of 2012 and 2013. In 2005, the department expressed increasing concern about complaints of malpractice, which had led to lawsuits ranging up to R216-million in the previous five years (Child, 2014:np).

This study is a sub study of a main study, "Retrospective Audit Analysis of Malpractice Litigation Cases in Nursing Practice in South Africa", ethics reference #N16\02\027.

The objectives of the main study #N16\02\027 are to identify the underlying factors which contribute to malpractice litigation (behavioural, clinical and organizational), including the severity and classification of adverse events and any other health professionals besides nurses that may have played a role.

Statistical correlations between the adverse events and the underlying factors will be done, as well as validated guidelines and solutions based on the scientific evidence will be introduced to improve the safety and quality of patient care.

This study will link into the main study #N16\02\027 by investigating the factors that contribute to malpractice litigation in nursing practice within the private healthcare sector of Gauteng. This will provide a foundation on which to formulate guidelines to contribute to the prevention of malpractice litigation in nursing practice.

The statistics of private health care remain unclear as there are no sources available. The majority of health-faced claims in the private sector are settled out of court. The pilot study of the main study (Stellenberg, EL., Whittaker, S., Esterhuizen, T., Gcawu, L., Samlal, Y. & Williams, A. 2016).

N16\02\027 has shown that of the 42 cases $n=29$ (69%) were private. The results further show that only $n=7$ (16.7%) were presented in court of which only three of these cases were private. The researcher has observed within clinical practice that patient safety becomes affected negatively when there is a shortage of nursing staff within the clinical field. Kang, Kim and Lee (2016:57) have found a correlation between the workload of nurses and nurse-perceived adverse events in patients. The nursing staff becomes pressurised to execute their designated duties in accordance to the standardised protocol of the specific institution. Daud-Gallioti, Costa, Guimaraes, Padilha, Inoue, Vanconcelos, Rodrigues, Barbosa, Figueriredo and Levin

(2012:12) conclude that nurse staffing is considered as a possible factor leading to health associated infections within an intensive care unit, as non-compliance to the nurses' patient care plans were identified. The high workload and insufficient nursing staff contributed to 50% of reported adverse events caused by human errors in Brazil (Daud-Gallioti *et al.*, 2012:12). Nurses are overwhelmed to provide the necessary patient care within the given time frame of their shift, which leads to negligence in patient safety and grounds for legal action. A decrease in workload could help nursing staff to focus more on the provision of quality care and patient safety (Kang *et al.*, 2016:59).

The quality of nursing care executed is largely dependent on the demeanour of the nursing practitioner. The findings of a study by Kim, Kim, Lee, Oh, Lee, Lim, Choi, Chung, Ryu, Jang and Choi (2015:5) in Korea confirmed that stress and fatigue were key elements which affected the competency of nursing respondents. The probability of human errors were more likely to occur in hostile environments. Performance was adversely influenced when personal problems were taken into account (Kim *et al.*, 2015:7). Intense circumstances have an impact on patient safety, as the patient has the right to be nursed by a competent practitioner at all times, in every environment, regardless of their emotional status (Kim *et al.*, 2015:7). Good decision-making in both routine and emergency settings is negatively affected in the presence of fatigue. Nursing practitioners who do not have sound judgement in a situation that requires specialised expertise may result in negligence behaviour which could have an adverse effect on the patient (Kim *et al.*, 2015:5).

Furthermore, Brasaite, Kaunonen, Martinkenas and Suominen (2016:1) state that various clinical environments and disciplines may also play a role in the attitudes of healthcare workers. Nursing practitioners may not utilize their skills to their full potential in an environment they do not feel comfortable in. Stress and emotional discomfort become highlighted in an environment where personal safety might be threatened, such as nursing a patient with mental disorders displaying unpredictable and violent behaviour (Brasaite *et al.*, 2016:1).

In addition to nursing practitioners losing confidence in intense clinical environments, competency also comes into play. Neale, Woloshynowych and Vincent (2001:328) describe that errors were made by trainee nurses who failed to identify clinical manifestations in patients within 24 hours of admission. This type of negligence leads to deficiencies in basic health care which could result in legal action. The contributing factors of these errors are the insufficient input from trained personnel in the presence of junior staff, who lack in training and supervision

(Neale *et al.*, 2001:329). Incompetent nursing practitioners present as a threat to patient safety as tasks are rendered without the necessary skills and knowledge.

According to Larizgoitia, Bouesseau and Kelley (2013:1) clinicians, patients, relatives and all the other members of the healthcare team must be willing to give a full account of the consequences that led to the harmful event.

In addition, healthcare institutions must analyse this information with urgency and provide feedback to all the parties involved, serving as a learning opportunity and creating a platform for improvement (Larizgoitia *et al.*, 2013:2).

Hwang and Ahn (2015: 16) state that teamwork is an essential component in providing high quality care in the healthcare delivery system. Better team communication is associated with an increase in nurses' error reporting performance (Hwang *et al.*, 2015:17). Increase in nurses' error reporting will reflect a reduction in patient safety risk and healthcare professionals are able to learn from the error. Nursing managers should become involved in facilitating teamwork and further encouraging adverse event reporting (Hwang *et al.*, 2015:17).

The background for the study is based on international literature and statistics within the public healthcare sector of South Africa. There is no evidence of any published literature or statistics regarding factors contributing to malpractice litigation in the nursing practice within the private sector of South Africa.

1.3 SIGNIFICANCE OF THE PROBLEM

The purpose of the study is to identify the factors that contribute to adverse events within nursing practice, leading to malpractice litigation in the private healthcare sector of South Africa. This could highlight areas of shortcomings in the delivery of safe quality patient care. Consequently, the results of this study could enable the development of guidelines and formulate solutions by policy makers and specialists, specifically in the private sector and the Gauteng province, as there would be a focus on the factors contributing to the litigation and the incidents classified according to its severity. Furthermore, factors contributing to adverse events leading to malpractice litigation in nursing practice could be emphasised in educational programmes taught at the relevant universities and nursing colleges.

1.4 RESEARCH PROBLEM

There is no clear description to clarify the factors leading to malpractice litigation in nursing practice within the private sector in South Africa. This poses a great burden to the healthcare system as there is no research available to combat the growing number of malpractice cases. Without any information as to the predisposing factors causing a breach in patient safety, there can be no guidelines put in place for improvement. Thus, the purpose of this study is to investigate factors that contribute to malpractice litigation in nursing practice.

1.5 RESEARCH QUESTION

The study was guided by the following research question:

“What are the factors that contribute to malpractice litigation in nursing practice within the private healthcare sector of Gauteng?”

1.6 RESEARCH AIM

The purpose of this study was to investigate factors that contributed to malpractice litigation within the private healthcare sector in Gauteng.

1.7 RESEARCH OBJECTIVES

The objectives for the study included:

To complete an audit of the nursing process documents of a trial bundle.

Categorising the adverse events according to principle type leading to malpractice litigation that involved nursing practitioners.

Identifying the factors contributing to the adverse events that have led to malpractice litigation, involving nursing practitioners.

Identifying the other members of the multi-disciplinary health team that played a role in the adverse event that has resulted in malpractice litigation.

Assessing the severity of the adverse event that has led to malpractice litigation.

1.8 CONCEPTUAL FRAMEWORK

A conceptual framework is a logical, abstract structure of meaning that guides the researcher to develop the study by linking the findings to knowledge currently used in nursing (Gray, Grove & Sutherland, 2016:154).

The Swiss Cheese Model, introduced by James Reason (1990), describes that within the healthcare organization there are many shortcomings leading to adverse events, compared to holes within slices of cheese.

Active failures and latent conditions are the reasons for the “holes” that are present within the barriers of healthcare.

Active failures are the unsafe acts committed by healthcare professionals who are in direct contact with the patient.

These unsafe acts can include the negligence of healthcare personnel with mistakes or lack of skills causing violations in procedure.

Latent conditions are the inevitable shortcomings within the healthcare organisation that lie dormant until it combines with active failures to create an accident opportunity.

These latent conditions can come in the form of understaffing, time pressures and inadequate equipment (Reason 2000:769).

The findings of the study have categorised the adverse events leading to malpractice litigation according to its principle type and primary cause, applying the active failures and latent conditions of the Swiss Cheese Model throughout.

1.9 RESEARCH METHODOLOGY

A brief account of the research methodology for this study will be described, followed by a detailed explanation of the methodology in chapter three.

1.9.1 Research design

For this study, a quantitative research approach was followed by applying a retrospective descriptive audit research design.

1.9.2 Study setting

The study was conducted at various law firms within the Western Cape and Gauteng Province.

1.9.3 Population and sampling

Malpractice litigation cases which have occurred in the private healthcare sector of Gauteng over a period of six years, 2011-2016, were selected by means of convenience sampling.

1.9.4 Audit instrument

A retrospective audit of the malpractice litigation cases was completed, using a validated audit instrument.

1.9.5 Pilot Study

For the purpose of this study a pilot study was done as part of the main study. The audit instrument was validated using the test-retest method and was applied in this study, with a few adaptations.

1.9.6 Reliability and Validity

The reliability and validity of the study were supported by a team of experts in the field of quality assurance and patient safety. The supervisor is a nursing expert in a court of law, with her focus research area being quality assurance and safe quality patient care.

1.9.6.1 Reliability

Reliability questions the measures of consistency within the study (Tappen 2010:126).

1.9.6.2 Validity

Validity is the extent to which the measure used by the researcher is true to its intended purpose (Tappen, 2010:139).

1.9.7 Data collection

The researcher collected all data after obtaining ethical approval from the Human Research Ethics Committee of Stellenbosch University and after permission was granted by various law firms specialising in malpractice litigation in health care.

1.9.8 Data analysis

A severity assessment code (SAC) rating was allocated to each malpractice case.

The data was analysed by using the SPSS statistical program which enabled the researcher to categorise into principle type and the factors.

1.10 ETHICAL CONSIDERATIONS

Ethical approval was sought prior to the study from the following organisations:

- Health Research Ethics Committee, Stellenbosch University (Appendix 2).
- Permission from law firms specialising in malpractice litigation in health care

The malpractice litigation cases remain the property of the specific law firms, thus the consent was requested from these law firms to allow the researcher access to trial bundles which met the criteria for auditing.

A waiver of consent was applied for from the Health Research Ethics Committee to allow the researcher to audit the malpractice litigation trial bundles without the permission of the hospital (defendant) or patient (plaintiff).

The following ethical principles were adhered to, according to the Helsinki declaration (World Medical Association Declaration of Helsinki 2008:3):

Anonymity and confidentiality were enforced throughout the study, names of doctors, attorneys, hospitals, hospital organization, patients or any names were not recorded.

Specific codes and numbers were given to represent demographic information and incident types. This further protected the anonymity and confidentiality of the patient, hospital organisation and law firm involved, as the study's main focus was solely to investigate the factors involving the specific malpractice litigation case.

There was no identification or linkage to personal information from the numbering and coding used during data collection. These were all removed once the data was processed on the

database to further ensure anonymity. Adverse events were not described which may have the possibility of being linked to a hospital.

All data collected and inserted into the database is protected by the security system of Stellenbosch University and only accessed by the researcher, supervisor and biostatistician involved in the study. In addition data will be accessed by the principle investigator of the main study and PhD student who will develop validated guidelines based on findings of malpractice litigation in nursing practice which occurred in private and public sectors. These guidelines may contribute to the prevention of malpractice litigation in nursing practice in South Africa.

1.11 OPERATIONAL DEFINITIONS

- Adverse event: an expected or unexpected event that results in a life-threatening event, extension of current hospitalization period, significant disability, congenital abnormality or death. This occurrence may be related or unrelated to medical intervention and treatment may require surgical or medical intervention (Hammaker, Knadig & Tomlinson, 2016:246).
- Preventable adverse events: a hospital-acquired condition that results in the patient experiencing serious harm (Hammaker *et al.*, 2016:246).
- Near miss: a patient safety incident that has not reached the patient. This is also viewed as a dress-rehearsal for an incident that could lead to possible harm (Webb, 2016:257).
- Medical negligence: a healthcare practitioner deviating from the medico-legal duty for care that leads to the harm of the patient (Iyioha & Nwabueze, 2016:67).
- Safety in nursing: minimizing the risk of harm to healthcare providers through individual performance and system effectiveness (Oster & Braaten, 2016:26).
- Patient safety: freedom from accidental harm at any point during the delivery of healthcare (Oster *et al.*, 2016:26).
- Malpractice litigation trial bundles: all the documents compiled by the claimant in preparation of a trial (Legal Technology: 2012, *np*).
- Safety assessment code matrix: method for the analysis of the key factors of probability and severity of adverse events and near misses (Varkey, 2010:62).
- Plaintiff: The victim that has suffered harm due to a breach in the duty of care (Buka, 2015:13).

- Defendant: Healthcare provider or healthcare organization in breach of duty of care (Buka, 2015:13).

1.12 DURATION OF THE STUDY

Literature review	Continuously
Pilot study	February 2016 - August 2016 (Main study)
Submission of proposal	September 2016
Ethics approval	January 2017
Data collection, capturing and analysis	March 2017 - October 2017
Writing of research report	October 2017
Submission of thesis	December 2017

1.13 CHAPTER OUTLINE

Chapter 1: Foundation of the study

Chapter one describes the foundation of the study which includes the significance of the problem, rationale for the study, research question, research aim and an overview of the research methodology.

Chapter 2: Literature review

Chapter two describes the literature review as applicable to the aims and objectives of the study.

Chapter 3: Research methodology

Chapter three gives the explanation of every process within the research methodology that was applied throughout the study.

Chapter 4: Results

Chapter four describes the findings of the study.

Chapter 5: Discussion, conclusions and recommendations

The findings of the study are discussed in chapter five, followed by recommendations based on the study's findings.

1.14 SUMMARY

Chapter one provides a short explanation of the ethical considerations and the operational definitions as applied in the study, also including a contextual, as well as a methodological overview which is further explained in chapter three. Chapter two is the literature review as applied to the objectives.

1.15 CONCLUSION

Malpractice is compromising the quality of healthcare in South Africa. Malpractice litigation cases are costing the country billions of rand annually, which could be better used to improve the shortcomings within the healthcare system. There are no clear indicators for the continuous escalation of malpractice litigation cases, thus enforcing the importance of the study and the value the information will be for the future.

CHAPTER 2

LITERATURE REVIEW

2.1 INTRODUCTION

A literature review can be described as a genre of writing in which the reviewer must create a body of work by deciding which studies to be excluded and included, as this decision will ultimately alter the conclusions drawn and the general theme of the review (Kennedy 2007:139).

The cornerstone to improve patient safety is about understanding the consequences and causes regarding incidents. Furthermore, providing adequate systems to facilitate the understanding of incident reporting systems across all healthcare sectors is crucial (World Health Organization (WHO), 2013:29).

In this literature review, the topic of adverse events will be discussed as it relates to the reasons why the adverse events occur and the factors that have an effect on the increase thereof, as well as the influences that adverse events have on the healthcare system and economy.

Search engines consulted in this literature review were Google and PubMed. Policies and statistics published by the World Health Organization and newspaper articles have also been consulted. Keywords include adverse events, medical errors, nursing attitudes, malpractice litigation and World Health Organization definition.

2.2 PATIENT SAFETY

Patient safety is a fundamental principle in the delivery of patient care and the quality of the management provided. In order to improve the state of safety in patients, a broad range of actions are required, including the safety of the working environment, the safe administration and use of medicine, the safety of equipment and safe clinical practice (WHO, 2004:4).

Patient safety has become an important global issue and has been recognized as a healthcare priority following the findings of several studies in the late 1990s, where reports have indicated the number of patients negatively affected due to adverse events were at its highest (Andersson, Frank, Willman, Sandman & Hansebo, 2015:377).

Despite the increased interest in the safeguarding of patients, there remains a lack of awareness of the problem pertaining to adverse events. The capacity for reporting and learning from past negative experiences are still hampered by the fear of professional liability, inadequate reporting schemes for the adverse event and the undue concerns of any breaches in the confidentiality of healthcare information (WHO, 2004:4).

2.3 ADVERSE EVENT

Hammaker *et al.*, (2016:246) define an adverse event as an expected or unexpected event that results in a life-threatening event, extension of current hospitalization period, significant disability, congenital abnormality or death. This occurrence may be related or unrelated to medical intervention and results in any of the following outcomes: a life- threatening event, inpatient hospitalization, extension of an already existing hospitalization period, a persistent or significant incapacity and disability or a birth defect, congenital anomaly and death (Hammaker *et al.*, 2016:246).

The risks to health do not occur in isolation, but include a chain of events that lead to an adverse health outcome. These include proximal factors which act directly to cause disease and distal causes which occur further back in that causal chain and manifest via a number of intermediary causes (WHO, 2002:13).

Medical negligence attorney, Karen Vermaak has stated in an article that one baby suffered brain damage due to poor obstetric monitoring of a woman in labour. The nurses did not detect the foetus being in distress and lack of intervention caused the infant being deprived of oxygen (Child, 2014:1).

Latino, Latino and Latino (2016:85) identifies the top 10 contributors to human error namely:

- Ineffective supervision within the identified workplace
- A lack of an accountability system
- A distractive environment including low alertness and complacency amongst employees
- Time pressure and work-related stress
- The overconfidence in execution of duties
- First-time task management
- Imprecise and unclear communication
- Incorrect and vague guidance

- A deficiency in training
- Introduction of new technology

The pressure to meet goals within the workplace can give rise to errors. The employees will make decisions based on the internal pressures they are experiencing and disregard the rules and procedures that are in place (Latino *et al.*, 2016:85).

Professor James Reason has been acknowledged with numerous awards with his publications starting as early as from 1961 that cover a range of subjects including: human error, safety culture and managing the risks of organizational accidents in healthcare and various other industries (Peltomaa, 2012:59). It is believed that people within the healthcare sector, doctors and nurses, do not make many errors but when they do, these result in accidents. This is not the truth because they do make a large number of errors daily which are mostly inconsequential. The true errors are due to the universal conditions within the system, including inadequate equipment, poor scheduling of staff members and under-manning (Peltomaa, 2012:60).

It is further explained that the most important aspect of error is recurrence and that the same situations can create the same type of error in different individuals. This concludes that more emphasis should be placed on error-prone situations than error-prone people, causing the staff members to become inheritors, rather than instigators of adverse events. The common error producing thread amongst the individuals is the human condition which cannot be changed, but the conditions under which these individuals work (Peltomaa, 2012:60).

People are prone to make errors that result in accidents. Within the healthcare environment, the errors and accidents lead to adverse outcomes and mortality (Boysen, 2013:400). Runciman and Watson (2007:112-118) explain that an error occurs when there is an unplanned deviation in treatment. These errors can be classified as it occurs in a particular context.

2.3.1 Errors in information

Many errors in the healthcare environment occur due to absent or incomplete information. The information may involve vital facts recorded in the patient's notes that never reaches the healthcare provider in time for proper decision-making to take place.

2.3.2 Errors in acquisition of knowledge

In the event that the required information is readily available, it is necessary that the healthcare provider has access to the information before commencing with treatment. The fundamental problem underlying many adverse events is treatment provided with an incomplete clinical picture.

2.3.3 Errors in perception

Errors in perception of crucial information may occur when the healthcare provider acts upon how they perceive information instead of how it truly is. The presentation of various drugs in ampoules of similar appearance can predispose to an adverse event where the information has not been properly inspected before providing treatment.

2.3.4 Errors in matching

One person's understanding of a scenario may not match another's and this is also applicable in healthcare. New medical information must be interpreted within the context of the patient's diagnosis, yet the healthcare provider may be fixated in his/her point of view and leave no room for difference of opinion.

2.3.5 Errors in knowledge stored as schemata

It is not possible for healthcare providers to know all the knowledge necessary to make insightful decisions. A threat to patient safety and delivering quality healthcare are errors in two primary types, namely: absent knowledge (knowledge that has been forgotten or never acquired) and incorrect knowledge.

2.3.6 Errors in knowledge stored as rules

Errors may arise when healthcare providers have created and stored identifiable patterns of responses to clinical situations. Adverse events may arise when the responses stored are not applicable to the individual needs of the patient.

2.3.7 Skills-based errors - slips and lapses

These errors manifest when a healthcare provider is interrupted when performing a vital task and has to start again from the beginning, resulting in unintended and inappropriate sequences.

2.3.8 Errors in choice of rule

Rules which are not intrinsically incorrect are incorrectly chosen and applied. One rule is utilized to treat all patients with the same condition, resulting in it being applied in an improper context.

2.3.9 Technical errors

Adverse events occur when there is a mismatch between the demands of the specific task and the skill of the healthcare provider. Technical errors involve the inability of the healthcare provider to execute their duties due to lack of expertise in the prevailing circumstances.

2.3.10 Deliberative errors

Errors occur when healthcare providers are faced with unfamiliar situations and realize there is no knowledge or rule to address it. The closest point of reference of a familiar scenario is then used as a basis for decision-making.

White and Ketrang (2001:42) explain that the traditional approach to dealing with adverse events by compiling new policies, retraining and imposing discipline will not remedy or prevent the recurrence of human error, instead it should start at grassroots level, where staff members are able to talk freely about identifying where errors are likely to occur and how the systems are facilitating these errors.

2.4 PUBLIC AND PRIVATE HEALTHCARE SECTORS

Pillay (2009:2) conducted a comparative analysis in the public and private health sectors of South Africa and has found that the public healthcare sector of South Africa is responsible for

the wellbeing of 82% of the population and accounts for only 40% of the total health expenditure. In contrast, the private healthcare sector consumes 60% of the health expenditure and is responsible for less than 20% of the South African population. The public sector is under sourced and overused, being characterized as being ineffective in meeting the criteria for affordable and accessible healthcare. On the other hand, the private sector of South Africa is reputed for outstanding care provision and its world-class facilities (Pillay, 2009:2). South Africa's two-tiered healthcare system differs in terms of intensive care. Intensive Care Units (ICUs) in the public sector are considered closed units in which the patients have to be accepted by a clinician in charge of the unit in order to be admitted. This is in contrast to the private sector which has open units and patients with varying levels of needs can be admitted by any clinician, with the appropriate ICU equipment readily available (Mahomed, Sturm & Moodley, 2017:12).

2.5 MEDICO-LEGAL LITIGATION

Globally, 10% of patients in healthcare facilities are negatively affected as a result of adverse events or preventable errors, and between 20 and 40% of funding is wasted due to poor quality of healthcare and failures in patient safety (Dhai, 2016:2). Medical malpractice in South Africa has increased, both in the amount and size of claims filed against healthcare practitioners, resulting in compassion-centred care being replaced with defensive medicine (Moore & Nöthling Slabbert, 2013:60).

The reason for the significant increase in malpractice litigation cases in the health sector is that patients have become more aware of their right to receive quality healthcare. The increase in litigation has a direct effect on the increase in the cost of indemnity insurance for the practitioners specializing in the private sector. Neurosurgery indemnity insurance being one example, has experienced an increase to the medical specialist for cover of 573 percent within a period of 8 years (Dube, 2016:1). The sustainability of obstetric care within the private sector of South Africa will soon become under threat as the inflation of malpractice claims has resulted in the increase of indemnity costs. This will result in private obstetric indemnity cover becoming unaffordable by the end of the decade (Howarth & Carstens, 2014:69).

Health Minister Aaron Motsoaledi has lodged a complaint regarding the shortage of specialised gynaecologists in South Africa and a warning issued by the South African Private

Practitioners' Forum informs that the shortage is becoming increasingly severe (Child, 2014:1). The rate of inflation related to healthcare has increased due to the consumers being forced to pay more for their subscription to medical aid. Doctors, especially neonatologists, obstetricians, neurosurgeons and orthopaedic surgeons have to increase their consulting costs to meet the huge indemnity fee they have to pay even before rendering medical care (Motsoaledi, 2015:6). The consequences of eliminating private obstetricians will be that an already busy public health sector will be placed under an increased burden where the labour ward will become busier with an influx of demanding patients (Howarth et al., 2014:69).

The financial budget of South Africa will be affected by the escalating costs of litigation, as more funds must be allocated to the healthcare budget. This will lead to an increase in taxes and negatively affect the public (Motsoaledi, 2015:6). The state does not budget for expenses due to litigation, thus the healthcare system of South Africa will suffer as every rand spent from the budget allocated for healthcare, is a rand that is no longer available to improve facilities (Howarth *et al.*, 2014:69).

The form of fault for medical malpractice will usually be due to negligence, but it may also include a range of other causes, including liability for the breach of contract, such as failing to perform an operation or procedure that was agreed upon or the invasion of privacy where the patient's medical details were disclosed to outsiders (Pepper & Slabbert, 2011:29). A number of causes may contribute to the increase in medico-legal litigation. The solution to addressing this issue requires a multi-disciplinary approach and involves investigating the system failures within the healthcare organization. The main focus should be the delivery of quality healthcare services and the competent management of patients (Dhai, 2016:2).

2.5 PROFESSIONAL NEGLIGENCE

According to Dhai and McQuoid-Mason (2010: 92) professional negligence can be defined as health practitioners failing to execute the care and skill required in the field of practice. Nursing practitioners have a great responsibility to perform their tasks within their scope of practice, as well as always acting in the best interest of the patient involved. The moment when the nurse acts irresponsibly and does not perform his or her tasks under the policies and procedural guidelines, the nurse can be held accountable for professional negligence. Griffith and Tegnah (2014: 202) discuss nurses' gross negligence by referencing a case in which two nurses were convicted of manslaughter, when an elderly patient died at a nursing home

(Sinclair, 2003). The resident sustained a pressure sore the size of a fist that lead to septicaemia and ultimately her death. A jury found the nursing manager guilty on the grounds of negligence while the resident was in her care.

In the event that medical negligence has taken place, in order for it to be proven, there are three elements to consider:

2.5.1 Duty of care

Armstrong, Bhengu, Kotze, Nkonzo-Mtembu, Ricks, Stellenberg, Van Rooyen and Vasuthevan (2013: 234) describe duty of care as an obligation that the health practitioner has in the specific role they function under, to ensure that others are taken care of. With the execution of every task, it is essential that health care practitioners practise a certain degree of care and consideration towards their patients.

Sokol (2006:1238) describes in a policy review in the United Kingdom, the phrase “duty of care” as being far too vague and can be regarded as ethically dangerous as the scope and nature of the duty of the healthcare worker need to be determined in order to recognize and acknowledge any conflicting duties. The healthcare worker’s speciality, the risk level of the working environment, as well as the competing obligations that stem from the healthcare worker’s multiple roles are all factors that limit the duty of care (Sokol, 2006:1238).

2.5.2 Breach of duty

The second element of medical negligence is the breach of duty. To prove that a nursing practitioner has acted negligently, the standard of care and policies has to be identified in order to confirm that she has executed her duties outside of those guidelines (Sanbar, 2007:254). Carroll (2009:117) explains that the healthcare worker will be found negligent if there was a breach in the stated duty that has made allowance for a hazard leading to the adverse incident.

Baranoski and Ayello (2008:35) explain that in order to establish a breach of duty element in a claim, the plaintiff in a medical malpractice case should be able to prove that the defendant healthcare worker deviated from the accepted standard of treatment or care. The healthcare worker should provide a level of care and expertise as required by the individual patient and any deviation in the standard of care provided must be established for the jury (a judge in the

South African legislation) and this is often with the help of expert testimony (Baranoski et al., 2008:35).

Baranoski et al., (2008:35) illustrates breach of duty within a healthcare setting in the following ways:

- The failure to provide care within the applicable practice act
- The failure to provide the standard of care for which the circumstances of the patient's condition requires
- The failure to perform professional duties with the expertise and degree of skill as stated in the applicable practice act.

2.5.3 Causation

This is the third element in medical negligence. Biggs (2010:67) describes causation as the primary complicating factor in medical negligence cases as it is difficult to establish that there were no other factors that could have been responsible for the harm in question. In all medical negligence cases, the plaintiff must be able to prove that the injuries sustained were due to a breach of duty. The test employed to demonstrate the causation of negligence is known as the "but for" test, in which the plaintiff must prove that "but for" the negligence, the injury or harm would not have occurred (Biggs, 2010:67).

According to Peterson and Kopishke (2010:111) when proving causation of negligence, there are several questions to consider:

- Was the negligence responsible for the injury or damage?
- Could the damage have been caused by external factors?
- Did the negligence cause all of the patient's injury or only a part?
 - If only a part was affected, which part?
- Is there any possibility that the outcome could or would have been the same in the absence of negligence?

2.6 DAMAGES

Civil liability is at issue when the plaintiff must be compensated (Para, 2011:102). Thus, when the plaintiff has experienced any form of monetary loss, sustained injuries or death, the plaintiff or her/his family is said to have experienced damages and the defendants may be found guilty

of civil liability, if the damages occurred as a direct result of not meeting the required standard of care (Kennamer, 2007:26).

Smith (2009:114) explains that there are two components to the awarding of damages to the plaintiff:

- *Economic damages* refers to any past or future monetary expenses of the plaintiff which include medical costs, loss of income and rehabilitation expenses
- *Non-economic damages* refer to damages in the form of pain and suffering.

Economic and non-economic damages are both known as compensatory damages as it is intended to provide a form of compensation to the injured plaintiff.

In contrast, *punitive damages* (also known as exemplary damages) are not awarded to compensate the plaintiff, but to deter and punish the conduct of the defendant where gross negligence and a reckless disregard for the safety of the patient were proven (Smith, 2009:114).

2.7 SAFETY ASSESSMENT CODE CATEGORIES

There are four Safety Assessment Code (SAC) categories that were utilized in assessing the severity of each adverse event:

- Extreme SAC 1 includes all clinical incidents where consumers with an outcome of death of causes unrelated to the identified illness or injury or has experienced treatment, differing from the desired outcomes provided from the healthcare institution. This includes adverse events where there was an increase in the length of the hospital stay with more than one hundred and twenty-five days. Serious shortfalls within the healthcare system were identified, intravascular gas embolism that has resulted in the neurological damage and death and the maternal death or morbidity associated with the labour or delivery process.
- Major SAC 2 includes all clinical incidents where moderate harm has occurred, specifically caused by health care provided and not that of the patient's condition or underlying illness. This includes the patient suffering permanent loss of either their motor, sensory or intellectual function, unrelated to the natural course of their illness. This is any result that required surgical intervention and an increase in the length of the hospital stay between twenty-five to one hundred and twenty-five days.

- Moderate SAC 3 includes all clinical incidents where minimal or no harm has occurred, specifically caused by health care provided and not the patient's condition or underlying illness, resulting in an increased stay in the hospital of between five and twenty-five days or requiring additional surgical intervention; this includes the failure to accurately treat a patient with broken skin, resulting in infection and additional surgery and the laboratory results not available to commence treatment.
- Minor SAC 4 patient/s requiring increased level of care that would include the need for more investigations and a referral to another health practitioner. This is an example of a patient falling and resulting in an abrasion.

(SA Health Risk Management Framework, nd).

2.8 VICARIOUS LIABILITY

After the plaintiff has successfully proven that the injuries sustained have been caused by the defendant and should be compensated for that harm, the question arises as to who would be held responsible for providing the compensation (Daly, Speedy & Jackson, 2010:168).

Moodley (2015:141) states that an employer may be held vicariously liable for any wrongful acts committed by an employee in the scope and course of that person's work. This will include the instances where the employer has warned against the use of certain procedures and where the employee has intentionally engaged in wrongdoing. Furthermore, a patient also has the right to bring about civil action against both the practitioner and hospital authority in question (Moodley, 2015:141). Vicarious liability is enforced where the healthcare employer will be the party that will be held responsible for the compensation of the damages of a plaintiff, but this does not nullify the defendant in their personal capacity, as the healthcare worker may be joined as a co-defendant (Daly et al., 2010:168).

The responsibility of the employer under vicarious liability applies to civil wrongs and does not apply to any criminal acts. Thus, a healthcare organization may be found vicariously liable for a nursing practitioner who commits a civil assault by administering an injection without the patient's consent, but not if the nursing practitioner angrily punches a patient (Daly et al., 2010:168).

2.9 LEGISLATION

2.9.1 The South African Constitution (Act 106 of 1996)

The South African Constitution (Act 106 of 1996) provides three sections for the right to healthcare, namely:

- Access to healthcare services including emergency services and reproductive health
- Basic health care for children
- Medical services for prisoners and detained persons.

2.9.2 The National Health Act

According to the South African National Health Act (Act No.61 of 2003), the right to healthcare is fundamental to the mental and physical well-being of every individual. The National Health Act (Act No. 61 of 2003) is based on the constitution of South Africa and provides a framework for a structured health system within the country, taking into account other laws, with regard to health services, on a national and provincial level. The aim of the National Health Act is to improve the national health system in South Africa with principles of equity, sound governance and have a shared responsibility among health professionals in both the private and public sector in the delivery of quality healthcare services.

The duties of the healthcare user include:

- The adherence to the rules of the healthcare establishment when treatment or health services is being provided
- To provide the healthcare provider with accurate information with regard to their current health status and give their full co-operation
- To treat all healthcare employees with respect and dignity
- To sign a release of liability or discharge certificate if recommended treatment is refused

The rights of healthcare personnel include:

- The healthcare personnel may not be unfairly discriminated due to their health status
- The head of the health care establishment may impose conditions on the service provided by the healthcare worker based on their health status
- The healthcare establishment is subject to implement measures to minimise any injury or disease transmission to the healthcare worker or damage to their property

- The healthcare provider may refuse to provide health care to a user who is physically, verbally or sexually abusive.

2.9.3 South African Nursing Council

The South African Nursing Council (SANC) is the controlling body that ensures the position of the patient within the healthcare system is safeguarded and has the function of setting the standard for performance within the nursing practice (Booyens, 2008:45).

The nursing practice of South Africa is governed under the Nursing Act (Act No. 33 of 2005) and in utilizing the Act, the SANC is able to regulate the practice of nursing and the professional responsibilities of the nursing practitioner (Booyens, 2008:45). The Nursing Act (Act No. 33 of 2005:7) states that the specific functions of SANC include the responsibility to ensure that nurses are respectful of the human rights of the healthcare users they are treating, conduct inspections to monitor compliance according to the Nursing Act and initiate disciplinary action where necessary.

There are two regulations that are promulgated through the Nursing Act which is in control of the activities of the nursing practitioner in South Africa. These regulations need to be taken into consideration in the development of procedures and policies, namely: Regulation 767 as promulgated through the Nursing Act No. 33 of 2005, setting out the acts and omissions of the practicing nurse and Regulation 786 published for comments (2014) setting out the scope of practice for nurses and midwives.

2.9.3.1 Regulation 767 of 1 October 2014: Acts and omissions

The acts and omissions as promulgated through the Nursing Act (Act No. 33 of 2005), which gives the SANC the authority to apply disciplinary steps against a nursing practitioner who is registered, where there is the failure to maintain the health status of a healthcare user under his/her care through:

- The assessment of the health status and responses of a healthcare user
- The administration of the correct and appropriate treatment
- The prevention of any trauma, injury or spread of disease
- The provision of specific treatment to the high risk healthcare users
- The monitoring of vital signs of the healthcare user

- Accurate record-keeping of all actions performed on the healthcare user.

2.9.3.2 Regulation 786 of 15 October 2013: Scope of practice

Section 30 of the Nursing Act (Act No.33 of 2005:25) sets out the scope of practice for the different categories within the nursing profession.

Regulation 786 (2013:5) describes the practice of nursing as being a dynamic process that provides and maintains the care of individuals, as well as communities that are faced with potential or actual health problems.

Furthermore, Regulation 786 outlines the nursing process which must include:

- Restore, support and promote the health status of the healthcare user
- Assist the healthcare user to maintain the basic activities necessary in their daily living
- Judgement is practised within a caring, therapeutic relationship
- Coordination and continuity of healthcare are maintained
- Continuous care and support are provided to the healthcare user through all stages of life, irrespective of their health state
- Provide and maintain a conducive and safe environment for healthcare

A *professional nurse* is a person who is qualified and competent to function independently and practise comprehensive nursing, at the level which is prescribed, assuming accountability and responsibility for rendered care.

A *midwife* is a person who is competent and qualified to independently practise midwifery, at the level which is prescribed, assuming accountability and responsibility for rendered care.

A *staff nurse* is a person who is educated to practise basic nursing at the level which is prescribed.

An *auxiliary nurse* or an *auxiliary midwife* is a person who is educated to provide elementary nursing care at the level which is prescribed.

Geyer (2016:51) states that the scope of practice for nurses and midwives is compiled to be a flexible framework. Consequently, it is to make provision to accommodate for different areas of nursing practice and allow for growth and developments in midwifery and nursing care. Therefore the scope of practice cannot be limited to a list to comply to, but rather broad guidelines setting out the regulation for the nurse or midwife, to allow for expansion and advances in the nursing and midwifery field (Geyer, 2016:51).

2.9.3.3 Unprofessional conduct

Section 46 of the Nursing Act (Act No.33 of 2005:32) outlines that any allegation or charges against a practitioner, owner of an agency, manager or director is to be investigated by The South African Nursing Council and penalties may be imposed. Furthermore, the Council may institute an inquiry into any allegation of unprofessional conduct that comes to its notice, without a formal charge or complaint.

Section 47 of the Nursing Act (Act No.33 of 2005:33) states that if the person registered is found guilty of unprofessional conduct, the Council is liable to impose one or more of the following penalties:

- A reprimand or a caution or both
- Suspension from the professional practice for a specified period
- The removal of the practitioner's name from the nursing practice register
- A prescribed fine
- The payment for the incurred costs of proceedings

Regulation 714 comprises of a notice in which the South African nursing council provides the details of the persons against whom disciplinary actions has been taken in terms of the Nursing Act

The statistical report by The South African Nursing Council for Professional Misconduct cases for the period March 2017 to November 2017 are as follows:

The Gauteng Province with eleven cases reported including two maternity related cases, two poor nursing care cases, one medication related case, three cases of forgery or theft, two cases of assault of patients or colleagues and one case of acting beyond the scope of practice. These stats are in comparison to the Western Cape Province with only three cases reported for the period.

The nursing category most involved in the cases of professional misconduct, was found to be registered nurses and midwives with the total amounting to twelve. The type of sanctions included five registered nurses and midwives were given effective suspension and six had their suspension further suspended.

There was an equal distribution between the enrolled nurses and enrolled nursing assistants involved in the professional misconduct cases, with a total of three. The sanctions included two enrolled nurses and three enrolled nursing assistants with suspension further suspended, respectively.

2.9.3.4 The Nursing Process

Weber and Kelley (2014:3-9) describe the phases of the nursing process as the holistic framework in which the nursing practitioner is able to identify and react to the individual needs of the patient. The process consists of five phases:

Phase 1: Assessment and collecting the subjective and objective data of the patient upon admission

Weber and Kelley (2014:3) explain that the health assessment is a vital stage in the nursing process as this is the starting point to evaluating the effectiveness of the nursing interventions and the quality of the patient's outcomes. This will involve analysing the data regarding the current health status of the patient, thus creating a nursing diagnosis and a framework for the provision of care.

The initial nursing report includes the collection and documentation of subjective data regarding the patient's perception of their current health status, health history and lifestyle practices upon admission. This is done in collaboration with the objective data collected during the physical examination of the patient (Weber & Kelley., 2014:5).

Phase 2: Diagnosis the analysis of the subjective and objective data in order to make a nursing diagnosis and referrals based on the nursing judgement.

The analysis of the data, also known as the nursing diagnosis, is the second phase. In order to effectively achieve the anticipated outcome of treatment for the patient, the nursing practitioner should ensure the data collected is thoroughly and accurately collected and documented. This phase is significant, due to the analysis of the data that could reveal the need for a referral to another discipline or the need for collaborative care of other practitioners (Weber & Kelley., 2014:9).

Phase 3: Planning a framework for the course of treatment is created based on the desired outcome criteria.

The nursing process utilizes the nursing diagnosis, the product of critical thinking and confirmed clinical judgement, as an initial platform to plan the course of treatment of the patient (Doenges, Moorhouse & Mirr, 2013:4).

Phase 4: Implementation the execution of the planned framework of treatment

In order to implement the plan for treatment, it is vital that the priorities for providing patient care is identified. As the care is provided, the monitoring and documentation of the patient's response to treatment and the communication of the findings with the other healthcare practitioners should be continuous (Doenges *et al.*, 2013:114).

Phase 5: Evaluation assessing whether the desired outcome criteria for the provision of care has been met and revising the plan as needed

Evaluation is an ongoing process and is necessary to discover the effectiveness of the treatment provided. As the patient's condition changes, this information is documented and there is a revision and updating of the plan of treatment, in accordance to the patient's individual needs and progress towards the desired outcomes (Doenges *et al.*, 2013:130).

2.9.3.5 Nursing progress reports

Initial report: In the initial report the nursing practitioner collects the comprehensive data reflecting the current health status of the patient (Doenges *et al.*, 2014:7). This would include the current state of the patient's health, as well as the patient's health history. If there is not an accurate and complete documentation of the patient's history, there cannot be an effective course of treatment, as every aspect of the patient must be assessed in order to produce an holistic treatment approach. The collecting of the subjective data is an integral part to obtaining a nursing health history. The subjective data provides the nursing practitioner with information regarding the psychological, physiological as well as the sociological issues that could possibly be present (Weber & Kelley., 2014:12).

Progress report: The constant measuring and monitoring of a patient's condition is vital to evaluate the patient's response to the nursing interventions and progress towards the desired

outcome (Doenges *et al.*, 2013:130). The progress report is the ongoing documentation of the patient's response to treatment and a lack thereof hinders the accurate reviewing of the desired outcome, as well as the patient's readiness for discharge.

The nursing practitioner manages the collaborative issues present in the patient's health by implementing both the medical practitioner and nurse-prescribed interventions. These collaborative efforts occur, because the nurse assesses and treats the patient holistically (psychological, physical, social, spiritual and cultural), involving the assistance of other healthcare practitioners (Weber *et al.*, 2014:9). Failure to report the changes in the condition of the patient to the medical practitioner has a negative effect on the course of treatment, as the immediate intervention has been delayed.

Discharge report. Discharge planning commenced at the admission of the patient to the healthcare setting and there are certain discharge criteria that patients and nursing practitioners must meet. These include adequate analgesia and pain control, stable vital signs, and no signs of active bleeding, obtaining a medical practitioner's discharge order and patient education. These must be accurately documented upon the patient's departure from the healthcare institution (Garber, Gross & Slonim, 2010:108).

The National Health Act, 2003 (Act 61 of 2003) states that the healthcare provider must provide the patient with a comprehensive discharge report at the time of their discharge; this would include an accurate documentation of the nature of the service rendered, the prognosis of the patient, as well as the need for any follow-up treatment. It is within this act that the nursing practitioner must comply and apply these principles within the nursing discharge reports (McQuoid-Mason & Dada, 2011:100).

2.10 FACTORS CONTRIBUTING TO ADVERSE EVENTS

2.10.1 Shortage of staff

The health sector is currently in a crisis in respect of human resources and it has been described as the most pressing issue affecting healthcare globally (Alluttis, Bishaw & Frank, 2014:1). The World Health Organization (WHO) has estimated that there is a global shortage of approximately 4.3 million nurses, doctors, midwives, and other members of the multi-disciplinary healthcare professionals. The WHO reports a number of eight physicians and forty-one midwifery and nursing personnel per 10 000 population in South Africa (van Vuuren & Mofokeng, 2014:1). The global shortage threatens the sustainability and quality of health

systems worldwide (Alluttis *et al.*, 2014:1). The shortage of nursing staff and practitioners in South Africa has resulted in an over-burdened healthcare system and may potentially be the reason for the increased number of medical negligence claims. The increased workload demand on healthcare worker may also account for a poor standard of medical care delivered, as they are prone to make mistakes, contributing to the negligence claims (van Vuuren *et al.*, 2014:1).

The shortage of nursing personnel in South Africa has forced the private sector to make use of international nursing staff to fill the vacancies. Nurses from countries like India are in high demand for the positions, but due to visa regulations and registration with The South African Nursing Council, these highly skilled practitioners are unable to enter the South African workforce (Dube, 2016:1).

The majority of hospitals instituted the twelve hour nursing shifts during the 1980s in order to increase recruitment and ease the scheduling of nurses' duties, as the idea of working three twelve-hour days within the week appealed more to nurses than five, eight-hour days weekly (Kennedy, 2014:7). This has significance as nurses are taking a second job at other hospitals or are being asked to work extra shifts if the hospital units are short staffed, leading to consequences that stem from prolonged hours and worker fatigue (Kennedy, 2014:7).

Bradley, Kamwendo, Chipeta, Chimwaza, De Pinho and McAuliffe (2015:6) have found in a study conducted at a Malawian hospital, that professional standards in obstetric care cannot be met due to a lack of skilled medical staff, forcing shortcuts in the medical care provided. The challenges of having a shortage of medical staff and too many patients were further exacerbated by the lack of skills needed to treat obstetric complications, mainly due to the locum doctors who do not have the adequate expertise to address an emergency (Bradley *et al.*, 2015:5). The nurse-midwives are obliged to act independently when identifying an obstetric problem and have to search for the medical officers, who are often not present, in order to secure the necessary care for their patients (Bradley *et al.*, 2015:5).

The transformation of the South African healthcare system is largely dependent on the effective utilization of the country's human resources, yet this remains a critical constraint in the deliverance of quality health care (Lagarde, Blaauw & Cairns, 2012:801). The shortage of registered nurses within South Africa is largely due to the more affluent countries offering the nursing practitioners better working conditions, registered growth and increased rewards and incentives (Mokoka, Ehlers & Oosthuizen, 2011:1). This is a particularly attractive offer as the burden of disease and prevalence of HIV and AIDS are lower within these developed

countries, but leave the remaining South African nurses to bear the brunt of working under pressurised circumstances.

Factors influencing the retention of registered nurses within the Gauteng Province of South Africa have found that 39.2% of registered nurses have responded that their intention to leave their health organizations were due to financial reasons. This includes the low salaries and poor overtime remuneration, as well as a lack of subsidies and benefits (Mokoka *et al.*, 2011:4). The results of a study conducted in the Free State have confirmed that despite the nursing shortage in South Africa, the majority of advanced midwifery practitioners were being under-utilized by not being placed in an area where their competencies and skills could be optimally recognized (Lesia & Roets, 2013:45). The lack of clinical practice will result in the deterioration of these specialized skills and result in advanced midwives immigrating to countries where they will be utilized and professional growth will be offered within the field (Lesia & Roets, 2013:46).

A study conducted within the intensive care units in South Africa has researched the nurse managers' views on staffing and found that the number of personnel members is not sufficient in comparison to the number of patients within the specialized area (Matlakala & Botha, 2016:53). This shortage in skilled staff members has a great effect on the quality of nursing care provided within the intensive care unit. Specialized care is being provided by staff members who are neither trained nor educated to do so. One participant expressed that due to the shortage of skilled intensive care registered nursing practitioners, the health organization relies on the skills of enrolled nurses to care for patients being ventilated (Matlakala *et al.*, 2016:53). In Frere Hospital in East London, the care of patients are at risk due to the shortage of nurses in the Intensive care unit. There should be a ratio of one intensive care nurse to one patient, due to the specialized needs the patient requires, but due to staff shortages within the hospital, the nursing staff are compelled to care for more than one patient (Tsewu, 2017:1).

Moonlighting, commonly understood as having at least one additional occupation in addition to the primary full-time employment, is on the rise among nursing staff and this includes the use of temporary agency nurses, which reports many negative consequences for service delivery within health sector (Rispel, Blaauw, Chirwa & de Wet, 2014:2). A study at 80 hospitals within the private and public sector of four South African provinces reported that critical care nurses reported a higher moonlighting rate in contrast with nurses in the

emergency units and theatre setting. This is a reflection of the high demand for skilled nursing care in both the private and public health sectors (Rispel *et al.*, 2014:6).

Daud-Gallioti, Costa, Guimaraes, Padilha, Inoue, Vanconcelos, Rodrigues, Barbosa, Figueriredo and Levin (2012:12) conclude that nurse staffing is considered as a possible factor leading to health associated infections within an intensive care unit, as non-compliance to the nurses' patient care plans were identified. The high workload and insufficient nursing staff contributed to 50% of reported adverse events caused by human errors in Brazil (Daud-Gallioti *et al.*, 2012:12).

De Beer, Brysiewicz and Bhengu (2011:8) explain the strategy of utilizing agency nurses to alleviate the staff shortages experienced within the intensive care units poses several challenges. The agency nursing staff lack the commitment, as well as the standard required to deliver quality care, as these nurses have not been exposed to the specialized environment and critically ill patients (De Beer *et al.*, 2011:8). The knowledge regarding the prevalence of agency nursing staff and moonlighting are important issues for many reasons, as these provide a reflection of the financial and time pressures faced by health care workers; provides an understanding of the negative consequences within the health system due to these phenomena (Rispel *et al.*, 2014:2). The high rate of bed occupancy within the intensive care setting, in combination with inexperienced nurses and critically ill patients provide an opportunity for adverse events (Michell, 2011:1).

2.10.2 Poor monitoring

The quality of medical and nursing care provided by the health practitioners of the Gauteng Department of Health is coming into question due to the numerous instances of poor monitoring and negligent acts, as reported by the patient reporting malpractice. A financial compensation of 23 million rand has been awarded to a mother due to prolonged labour and failure to perform a caesarean section at Chris Hani Baragwanath Hospital, which has left her seven year old son with permanent brain damage. The cause was due to negligent treatment by the relevant medical doctors and nurses involved (Sidimba, 2017:1).

Poor monitoring and negligence in medical care are not solely the cause of incompetent medical practitioners, as the death of 300 oncology patients in KwaZulu-Natal has been a result of the chronic shortage of specialists and the lack of specialized equipment required to provide quality treatment (Olifant, 2017:1). The Minister of Health Aaron Motsoaledi stated

that the procurement of services and human resources to be the primary cause of the oncology crisis being faced in KwaZulu-Natal (Mthethwa, 2017:1). The South African Human Rights Commission has found that the rights of these oncology patients to access quality healthcare have been infringed and the state of healthcare services within the provincial, as well as the national health departments acted unlawfully (Olifant, 2017:1). The Minister of Health further explains that non-functioning oncology machines is one of the symptoms second to the root cause which is planning and development, as there are not enough oncology specialists available (Mthethwa, 2017:2).

The South African courts have recognized that quality healthcare cannot be expected which is beyond the financial resources of the hospital (Moodley, 2015:141). It is detailed in the South African Health Review of 2017, that the weak South African economy is indirectly affecting the employment of doctors and nurses, as posts are being frozen to save money and manage the budget (Child, 2017:1). Furthermore, health analysts and Treasury members predict a decline in the health budget of South Africa, with spending to decrease up to 2.2% between the period of 2015 and 2019, resulting in the delay of maintenance and building of health facilities (Child, 2017:2).

2.10.3 Lack of training

The medical negligence experienced in the South African private and public sectors was caused by the nursing staff displaying characteristics of poor training and negative attitudes (Child, 2014:1). A medical negligence attorney has reported that under-qualified nurses are working in intensive care units in private hospitals and specialized care is not up to standard; one specialized nurse monitors four babies, instead of a one-to-one nurse-to-baby ratio. A study of the perceptions of primary healthcare workers providing care to mental health users in Vhembe district, Limpopo Province, South Africa have found that the majority of the participants were not qualified in psychiatric nursing and were left alone in the clinic to provide a service to the mental healthcare users (Shilubane & Khoza, 2014:382). Out of the forty-five participants, there were only thirteen primary healthcare workers that were qualified psychiatric workers, which reflects that mental healthcare users were managed by workers lacking the competence and skill to ensure quality care. The majority of the participants explained that it is a challenge to provide quality care to the mental health users in the absence of the multi-disciplinary team members, which would include the Social Worker, Psychiatrist,

Clinical Psychologist and Occupational Therapist (Shilubane & Khoza., 2014:383). This contributes to a variety of factors which influence the provision of quality nursing care, including the inequities regarding the distribution of resources and nursing staff (Shilubane & Khoza., 2014:378).

2.10.4 Lack of adherence to policies

A study conducted in two district hospitals in Rwanda has identified lack of adherence to standards and guidelines for postpartum care management factors influencing the job performance of midwives and nurses in postpartum units (Uwaliraye, Puoane, Binagwaho & Basinga, 2013:59). The high rates of postpartum complications, as well as the patients' complaints regarding the quality of nursing care within the maternity unit were reflections of the lack of adherence to policies that provide the necessary procedures to prevent life-threatening complications after birth (Uwaliraye et al., 2013:67).

2.10.5 Professional ethics

The patients' and doctors' trust in the nursing practitioners' ethical ability, theoretical and clinical skills have come into question after thousands of qualified nursing practitioners may have cheated in their May 2017 examinations provided by The South African Nursing Council (Child, 2017:1). Staff nurses who are already working at clinics and hospitals have pursued a two-year course that, upon completion, will qualify them to become registered nurses. A position that requires more expertise to be able to function independently and accept more responsibility (Child, 2017:1).

Professor Aimes Dhai, Director of the Steve Biko Centre for Bioethics has expressed that the suggestion of cheating amongst nurses raises concern about their adherence to the Florence Nightingale Pledge, which states that the nursing practitioners will abstain from any mischievous practices and practice faithfully. This would also create a feeling of anxiety amongst patients as the relationship of trust in the nurses' knowledge and competency is now eroded (Child, 2017:2).

2.10.6 National budget and procurement

Makgoba (2017:1) states the findings of the Health Ombudsman which has reported the unlawful deaths of more than ninety-four mentally ill patients in the Gauteng Province between the 23rd March 2016 and 19th December 2016. This number has escalated to one hundred and one deaths. The mentally ill patients were transferred from Life Esidimeni to twenty-seven non-government organizations (NGOs), which operated under invalid licenses, in order to save on costs allocated to mental-health users in the health budget. The patients were taken from a healthcare environment that was structured and provided a caring atmosphere to newly-established NGOs which were poorly prepared with staff members that were not qualified for the highly specialized continuous care required for the mentally ill patients (Makgoba, 2017:2).

Following this incident, more than 50 psychiatric patients presently still reside in unacceptable conditions that could result in another tragedy. These patients were allocated to four wards within Weskoppies Hospital in Gauteng with a shortage of beds, malfunctioning sewerage and compromised infrastructure that pose a danger to their lives (Nzimande, 2017:1).

2.10.7 Just culture

Boysen (2013:400) describes a just culture in health care as balancing the need for an open and honest reporting system within a quality learning environment. The health organization ultimately has a responsibility towards the patients and a shift from errors towards the management of behavioural choices amongst healthcare providers, ensures a just culture in health care (Boysen, 2013:400).

To effectively deal with the stress and emotions of staff members, a safety culture needs to be established within the working environment, where the staff members share the same set of values for safety and positive communication to take place (Woodward, Randall, Hoey & Bishop, 2004:47). Debriefing is essential amongst health practitioners and should be enforced once a day on every shift. Appointing a specific time and place where the day's tasks and the staff members' opinions on incidents that have occurred can be discussed, unity and a sense of teamwork will be created. Every staff member should have a fair and equal chance to speak their minds and have a platform for their concerns with regard to patient safety (Woodward *et al.*, 2004:47).

2.10.8 Attitude of nurses

A study conducted in private general hospitals in Gauteng, South Africa has found that the nursing participants have perceived themselves as being insensitive and not in full awareness of the emotional needs of their patients (van den Heever, Poggenpoel & Myburgh, 2013:6). This confirms the historical generalization and recent media coverage that nurses do not provide holistic care, which includes the physical, mental, emotional and spiritual needs of the patient.

Nursing staff working with patients that have an intellectual disability in the Free State Psychiatric Complex, South Africa has confirmed that the high workload is one of the main occupational stressors they experience. The study identifies various other occupational stressors, which include the endangerment of their personal safety and physical health, pressure experienced from management, under-appreciation of skills and underpayment for services (Conradie, Erwee, Serfontein, Visser, Calitz & Joubert, 2017:6). The performance expectations are much higher in nurses working within a psychiatric setting than nurses in other disciplines, thus these nurses are more likely to experience burnout and stress, negatively influencing their physical health and quality in the execution of their duties (Conradie *et al.*, 2017:3).

In a survey conducted nationally by the Aids Healthcare Foundation, the primary barrier to people not receiving HIV treatment is the judgmental attitudes and rude, uncaring manner in which the nurses conduct themselves. The poor attitude of nurses is largely responsible for the lack of compliance to treatment (Seid, 2017:1). One of the respondents revealed that the nurses spread rumours and that there is no privacy within the HIV diagnosis and treatment process (Seid, 2017:2).

2.10.9 Adverse event reporting

If organizations are to improve the culture of reporting incidents amongst staff members, a number of barriers must be overcome namely: the clinical staff becoming anxious about being blamed, as well as the time it takes to submit an official report and what management will do with the information once they have it.

Most importantly, to reassure staff members that the process is worthwhile and that it can make a difference to practice (Woodward *et al.*, 2004:87).

Woodward *et al.*, (2004:87) explains the benefits of incident reporting:

- Resources targeted more effectively

Reported incidents provide evidence that identifies areas for change in order to use resources more effectively in both patient safety and patient care.

- Increased responsiveness

Timely reporting can increase the level of responsiveness of addressing adverse events, particularly when undertaking investigations.

- Pre-empting complaints

Organizations can prepare proactively for potential litigation cases and complaints by providing patients with more detailed information on patient safety. This may lead to fewer complaints, saving time and resources.

- Reducing costs

There are financial benefits that arise from reduced severity of incidents, e.g. reduced length of stay for the patient and reduced costs of treatment

2.10.10 Media influence on healthcare

South African society has placed unrealistic expectations and demands on healthcare workers in the public sector without being aware of the harsh working conditions. Doctors need to improvise with insufficient and inadequate equipment and supplies, yet still provide quality healthcare. The rights of healthcare workers have been forgotten and responsibilities have been increased, leading to feelings of dissatisfaction (Nicolaou, 2010:10).

Whitten, Dutta, Carpenter and Bodie (2008:1) have found that the media is using adverse events to sensationalise the news, at the expense of the health profession. The media is often unfamiliar with the correct medical terms causing the misinterpretation of facts being reported to the public (Whitten *et al.*, 2008:1). Misinterpretation and subsequent reporting instil mistrust in the patients and fear amongst medical professionals. Patients start to doubt the competency of the medical professionals by adopting a sense of bias.

Young, Norman and Humpreys (2008:10) explain that diseases that have had repetitive, continuous media exposure are perceived more threatening than diseases less mentioned in the media, but with equal severity. The media has a significant influence in the manner the public shapes their opinion regarding medical issues. The function of the media should be to raise public awareness of health concerns, instead of irrationally causing alarm, as an

estimated 11% of articles printed in the news include claims that have been exaggerated (Young et al., 2008:11). Litigation is pursued when patients are dissatisfied with the healthcare they have received. With the increased misconceptions made by the media, the public pressurises healthcare professionals to meet unrealistic expectations.

Media reports providing a negative reflection on the nursing profession might have an influence on the public's perception of nurses. The media takes the negative experiences of patients and their family members and sensationalizes these events, resulting in a poor public image of the nursing profession and deterring young people from considering nursing as a career option (Meiring & Van Wyk, 2013:4).

2.11 SUMMARY

In this chapter, the researcher has reviewed published literature, which includes quantitative and qualitative studies, textbooks and newspaper articles. The factors influencing adverse events that lead to malpractice litigation have been highlighted.

2.12 CONCLUSION

The literature review in this chapter has enabled the researcher to become familiar with the findings of existing literature on both an international and national context. The aim of the literature review was to provide insight and familiarity in the field of malpractice litigation and the relevance of the nursing practice as a contributing factor.

CHAPTER 3

RESEARCH METHODOLOGY

3.1 INTRODUCTION

In chapter two, the literature review created a foundation to the development of the research methodology used in this study and highlighted the various issues regarding adverse events and how it relates to malpractice litigation within the South African context.

In order to explore the factors influencing adverse events leading to malpractice litigation, a descriptive quantitative approach was applied. Malpractice litigation trial bundles were audited, congruent to the research objectives.

3.2 RESEARCH OBJECTIVES

Gray, Grove and Sutherland (2016:691) define a research objective as the researcher's formal stated goals for the study or the desired outcomes.

The objectives for the study include:

- To complete an audit of the nursing process
- Categorising the adverse events according to principle type leading to malpractice litigation that involved nursing practitioners.
- Identifying the factors contributing to the adverse events that have led to malpractice litigation, involving nursing practitioners.
- Identifying the other members of the multi-disciplinary health team who played a role in the adverse event that has resulted in malpractice litigation.
- Assessing the severity of the adverse event that has led to malpractice litigation.

3.3 STUDY SETTING

LoBiondo-Wood and Haber (2014:101) describe a study setting as the place where participants are recruited and the setting where the data for the study is collected.

The study was conducted at various law firms, within the Western Cape and Gauteng Province, after permission was granted. Each law firm had a conference room where the trial bundles were audited.

3.4 RESEARCH DESIGN

For the study, a quantitative research approach was followed by applying a retrospective descriptive audit research design. Grove, Burns and Gray (2013:215) define a descriptive study design as a means to gain more information about characteristics within the specific field of study.

A descriptive design may be used to identify problems within practice, make judgements or determine what is being done in similar situations (Grove et al., 2013:215).

The descriptive quantitative approach involved interpreting the results from the malpractice trial bundles and presenting the results in graph and frequency formats, whilst including a descriptive aspect to enrich the data of each individual malpractice trial bundle. The malpractice trial bundles included all the legal, medical and nursing documents pertaining to each individual case, from both the defendant and the plaintiff.

3.5 POPULATION AND SAMPLING

Grove, Gray and Burns (2014:250) define a population as being a particular group of elements or individuals which becomes the focus of the research. In the event that a total population of a study is too small, it would be advisable to utilize the entire population, as sampling of such a small size would not be possible (Strydom, 2005:195).

Malpractice litigation cases which have occurred in the private healthcare sector of Gauteng over a period of six years, 2011-2016, were selected by means of convenience sampling. In convenience sampling, subjects are included simply by being in the right place at the right time (Gray, Grove & Sunderland 2016:343).

The malpractice litigation trial bundles contained evidence ranging between 500 and 2000 pages. This included expert witness opinions, clinical records as well as statements from the plaintiffs and defendants.

The biostatistician, a co-investigator of the main study #N16\02\027 advised that law firms specializing in malpractice litigation in health care who managed malpractice litigation cases which occurred in Gauteng be approached. A convenience sample could then be drawn from available cases. A total of thirteen law firms who specialise in malpractice litigation were approached and only those who gave consent to participate in the study were included. The law firms requested that strict anonymity and confidentiality be maintained.

A power analysis with the support of the biostatistician of the main study #N16\02\027 was done which identified that a total of 400 cases would be required to complete the main study #N16\02\027. These cases would be divided amongst the sub investigators of the main study #N16\02\027, namely one PhD student and two Master's degree students. A total of 200 cases would be audited by the PhD student, who would investigate malpractice litigation which occurred in public hospitals in Eastern Cape and Gauteng. The Master's degree students would each be auditing 100 malpractice litigation cases which occurred in private hospitals, in the Western Cape and Gauteng provinces respectively.

Due to the sensitivity of the data that was collected, a total number of forty-one trial bundles were made available to audit. These trial bundles ranged from eight to twelve folders per court case and comprised of pleadings, hospital records and expert witness testimonies.

3.5.1 Inclusion criteria

Inclusion sampling criteria are characteristics that the element or subject must possess in order to form part of the target population of the study (Grove, Gray & Burns, 2014:251).

Malpractice litigation cases, either heard in the South African High Courts or settled out of court in South Africa, specifically only litigation cases which involved the private hospitals within the Gauteng Province were included in the study. Only cases which have been finalized and completed were included.

3.5.2 Exclusion criteria

Exclusion criteria are characteristics which allow the researcher to exclude an element or person from the target population (Grove, Gray & Burns, 2014:251).

Any malpractice litigation case that was used in the pilot study or involving the road accident fund was excluded from the proposed study. In addition, cases that had received a lot of publicity and might be identifiable were also excluded.

3.6 INSTRUMENTATION

An audit instrument was used to audit the malpractice litigation cases based on the objectives of the study. The data was mapped onto the audit instrument and then captured electronically onto the excel spreadsheet.

The audit instrument was divided into six sections which guided the auditing process.

The sections were aligned to the objectives as follows: The sections of the instrument were aligned as follows:

- Sections A-D were linked to objective 1
- Sections E and F were linked to objectives 2-5
- Section A: Includes questions regarding the litigation
- Section B: Demographic data of the patient
- Section C: Questions describing the hospitalisation period
- Section D: Operating room information
- Section E: Adverse event(s) information
- Section F: Factors contributing to the adverse event

Objective 1 included the assessment of the nursing records and auditing of patient care plans and treatment reports, which included details pertaining to the litigation, the demographic information of the patient, hospitalisation period and operating room information (if applicable to the individual case).

Objectives 2-5 include section E and F of the audit instrument.

Section E described the details regarding the adverse event. This included the environment where the adverse event occurred, the outcomes experienced by the plaintiff, as well as the members of the multi-disciplinary health team that may have played a role and the severity of the adverse event.

Section F identified the adverse event according to its principle incident type, indicated the severity of the adverse event according to the Safety Assessment Code Matrix and identified the factors that have contributed to the adverse event.

3.7 PILOT STUDY

For the purpose of this study a pilot study was not done as this was done in the main study. The audit instrument used to perform the pilot study was compiled by the principle investigator, co-researchers and sub-investigators of the main study (Ethics reference number: N16/02/27).

3.8 RELIABILITY AND VALIDITY

The reliability and validity of the study are supported by the legal inquiry of various experts in the field of nursing and medicine. This included the expertise of advocates and attorneys attending to the malpractice litigation cases.

The rigor of the study is further supported by a team of experts in the field of quality assurance and patient safety, providing their own opinion on each case being audited.

The supervisor is a nursing expert in courts of law, with her focus research area being quality assurance and quality of patient care.

3.8.1 Reliability

Reliability questions the measures of consistency within the study (Tappen 2010:126).

These questions include:

- If two individuals are using the same measure, in the same situation, will they get the same result?
- If the individuals use the same measure on two different occasions, will the result be the same?
- Are all the questions within the measure measuring the same phenomenon in the same manner?

If any of these questions were answered by “no”, the measure or usage of the measure is deemed unreliable.

The pilot study formed part of the main study (#N16\02\027). The reliability of the audit instrument was tested during the pilot study by applying the test-retest method. This means that the measuring instrument will be able to produce consistent results by various researchers, in similar conditions (Delpont, 2005:162).

The audit instrument thus applied in this study was slightly adapted by only deleting one question about whether the case was private or public. For the purpose of this study the emphasis was on private cases only and this question was not required.

The researcher, as a sub-investigator of the main study, participated in the auditing process during the pilot study and was able to identify modifications needed to ensure the reliability of the audit instrument. Once the verification was complete, the information was captured onto an electronic spreadsheet which included consultation with the biostatistician, one of the co-investigators of the main study who assisted with the data analysis.

3.8.2 Validity

Validity is the extent to which the measure used by the researcher is true to its intended purpose (Tappen, 2010:139).

3.8.2.1 Content validity

Refers to the measure which includes all the dimensions necessary for the phenomenon to be measured and does not include any irrelevant information. The researcher should have extensive knowledge regarding the subject of the study and its dimensions and boundaries. All the necessary literature has been consulted in the development of the auditing instrument (Tappen, 2010:140). For the purpose of this study the content of the audit instrument was based on the objectives and guided by the conceptual theoretical framework. The co-investigators of the main study evaluated the content to ensure that it met the objectives of the study. Literature was consulted, as well as experts in the field of safe quality patient care so that all elements to be measured were included in the audit instrument.

3.8.2.2 Face validity

Face validity as described by Grove, Burns and Gray (2013:394) refers to the instrument that it appears to measure; the construct it is supposed to measure. The co-investigators of the main study, experts in quality assurance and the biostatistician agreed that the instrument was valid and that it appears to meet the requirements of the study.

3.9 DATA COLLECTION

Keele (2010:27) defines data collection as decisions that include the sample and study population, getting all the necessary approvals needed to do the study and deciding on what data will be collected in order to answer the research question.

Data collection was commenced after the researcher obtained ethical approval from the Human Research Ethics Committee of Stellenbosch University and once permission was granted by various law firms specialising in malpractice litigation.

In order to obtain the data required for the study, the researcher had to approach law firms specialising in malpractice litigation. The majority of malpractice litigation cases in Gauteng were represented by law firms in Cape Town, thus the researcher had to travel to Cape Town, as well as Gauteng for data collection.

A total of fifteen law firms were contacted telephonically and via electronic mail from the period between March and September 2017. A letter requesting consent to access the malpractice litigation cases they have represented was sent.

A waiver of consent was obtained from the Human Research Ethics Committee, in order to allow the researcher to audit the malpractice litigation bundles without the consent of the patient or hospitals. Once consent was granted, the researcher audited the malpractice litigation trial bundles using the audit instrument. The law firms requested that no written consent be recorded and added to the thesis, as this breaches the confidentiality agreement between their clients and the identity of the law firms would be exposed, jeopardising their professional reputation. The researcher approached the law firms personally once ethical approval had been obtained.

Due to the sensitive nature of the data, the law firms were reluctant to participate in the study. The primary reason being that they were not comfortable to reveal any of their client's information or the amount for which the court case had been settled. This decision was made out of fear that their business and most importantly, their revenue, would be negatively affected.

A total of five law firms, between the Gauteng Province and Western Cape agreed to participate in the study. The researcher travelled to the individual law firms and did the auditing of the files at the premises of the various law firms; none of the trial bundles were removed from the law firms.

All malpractice litigation cases aligned with the criteria were used in the study.

3.10 DATA ANALYSIS

Antonius (2003:34) describes descriptive statistics as a means of providing meaning to a situation by summarizing information that emphasises the important numerical features of the particular data.

Muijs (2010:1) defines quantitative research as explaining a particular phenomena by collecting numerical data, analysed by means of mathematically based methods. In this study the method used was the Statistical Package for Social Sciences (SPSS). SPSS produces charts, tables as well as numerical statistical measures that must be interpreted and the data must be specified in line with the study objectives (Antonius, 2003:30).

The data was analysed by using the SPSS statistical program where the information inserted was already categorised into principle type and the factors after data collection.

The data obtained from the trial bundles were interpreted with the support of a bio-statistician. The data is presented in chapter four in frequencies, organised by means of figures and tables, to provide a visual representation and descriptive information according to the results of each question in the audit instrument, in line with the objectives of the study.

3.11 SUMMARY

The research methodology and how it relates to the aims and objectives were described within this chapter. The description of the data collection, data analysis as well as the reliability and validity enhanced the credibility of the study. In chapter four, the findings of the study are presented.

3.12 CONCLUSION

This chapter explained the research methodology as it is applied to the research design, population and sampling, audit instrumentation, pilot study as well as the reliability and validity. This also included the data collection and data analysis process.

Chapter four will describe the data analysis process, as well as the visual interpretation of the research study findings.

CHAPTER 4

DATA ANALYSIS, INTERPRETATION AND DISCUSSION

4.1 INTRODUCTION

This chapter outlines the analysis, interpretation and discussion of the quantitative data collected during the research study. For the study, a quantitative research approach was followed by applying a retrospective descriptive audit research design. Grove, Burns and Gray (2013:215) define a descriptive study design as a means to gain more information about characteristics within the specific field of study.

The descriptive quantitative approach enabled the researcher to interpret the data analysed based on the results obtained from the malpractice trial bundles. The malpractice trial bundles included all the legal, medical and nursing documents pertaining to each individual case, from both the defendant and the plaintiff.

4.2 DATA ANALYSIS

The Statistical Package for Social Sciences (SPSS) was applied to analyse the data. SPSS produces charts, tables as well as numerical statistical measures that must be interpreted and the data must be specified in line with the study objectives (Antonius, 2003:30).

The results of the audit of the trial bundle were interpreted with the support of a bio-statistician. The data are presented in frequencies, percentages and organised by means of tables, to provide a visual representation and descriptive information.

A total of forty-one trial bundles were audited at various malpractice law firms that gave their consent to the researcher to access their documents. For the purpose of this chapter the plaintiff will be referred to as the patient.

4.3 SECTION A: THE LITIGATION

Section A of the questionnaire represents the details of each court case.

4.3.1 Question 1: How was the court case presented?

All the court cases $n=41(100\%)$ that were audited were settled out of court.

4.3.2 Question 2: If presented in court, indicate which High Court.

All cases were settled out of court.

4.3.3 Question 3: If settled out of court, indicate the amount for which the case has been settled.

All the cases were settled out of court and the quantum was not available to the researcher.

4.3.4 Question 4: If presented in court, indicate the outcome of the judgement (quantum to be paid).

This question is not applicable as all cases were settled out of court.

4.4. SECTION B: DEMOGRAPHIC DATA OF THE PATIENT

Section B of the questionnaire requires the demographic data of the patients involved in each court case.

4.4.1 Question 5: Age

Table 4.1 shows that n=11(26.8%) of the patients were aged between 0-9 years followed by n=9(22%) whose ages ranged between 50-59 years and n=8(19.5%) 40-49 years.

Table 4.1: Age

Age	Frequency	Percentage
0- 9 years	11	26.9
10- 19 years	1	2.4
20- 29 years	3	7.3
30- 39 years	6	14.6
40- 49 years	8	19.5
50- 59 years	9	22
60-69 years	2	4.9
70-79 years	0	0
80- 89 years	1	2.4
Total	41	100

4.4.2 Question 6: Gender

The majority of the patients were female, $n=21(51.2\%)$ and $n=20(48.8\%)$ were male as shown in figure 4.1

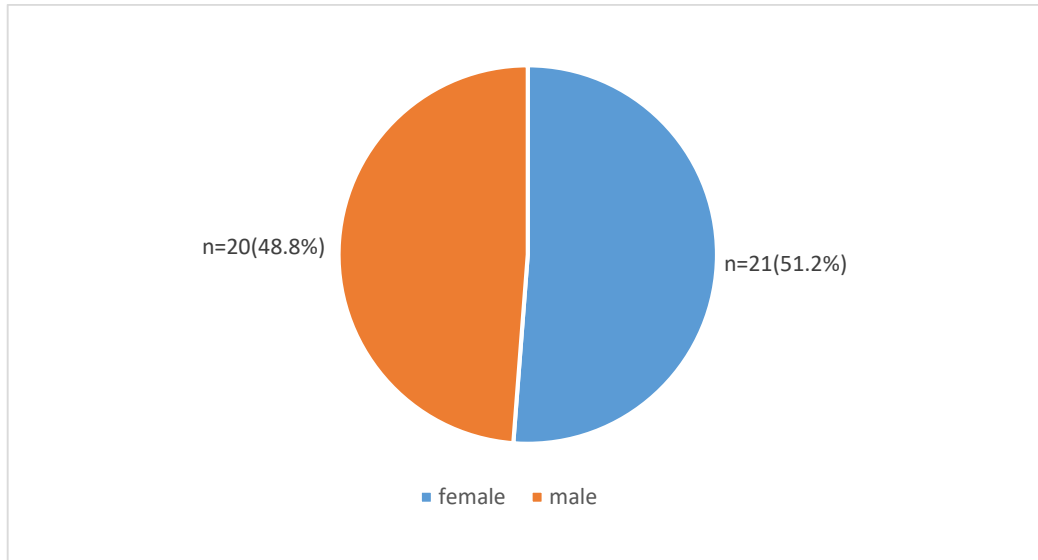


Figure 4.1: Gender

4.4.3 Question 7: Marital status

Figure 4.2 shows that the majority of the patients were married $n=22(53.7\%)$ with $n=6(14.6\%)$ single.

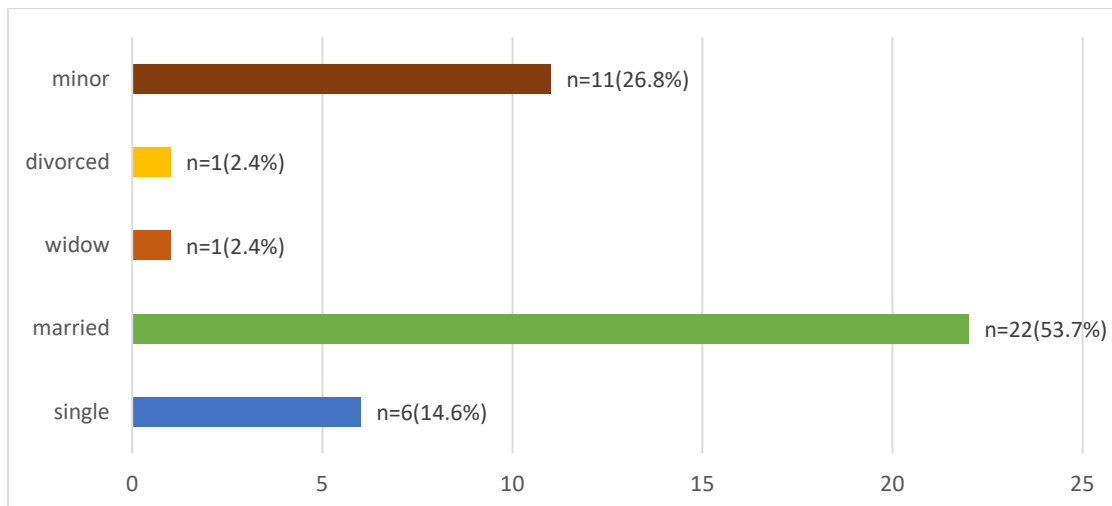


Figure 4.2: Marital status

4.4.4 Question 8: Dependants

Table 4.2 shows the number of dependants of each patient. Ten of the patients had two dependants $n=10(24.4\%)$. Eleven (26.8%) trial bundles had a minor as the patient.

Table 4.2: Dependants

	Frequency	Percent
none	3	7.3
one	6	14.6
two	10	24.4
three	1	2.4
>3	2	4.9
not documented	8	19.6
minor	11	26.8
Total	41	100

4.4.5 Question 9: Any disability on admission

Only $n=2(4.9\%)$ patients had a form of disability before being admitted to receive health care, as shown in figure 4.3.

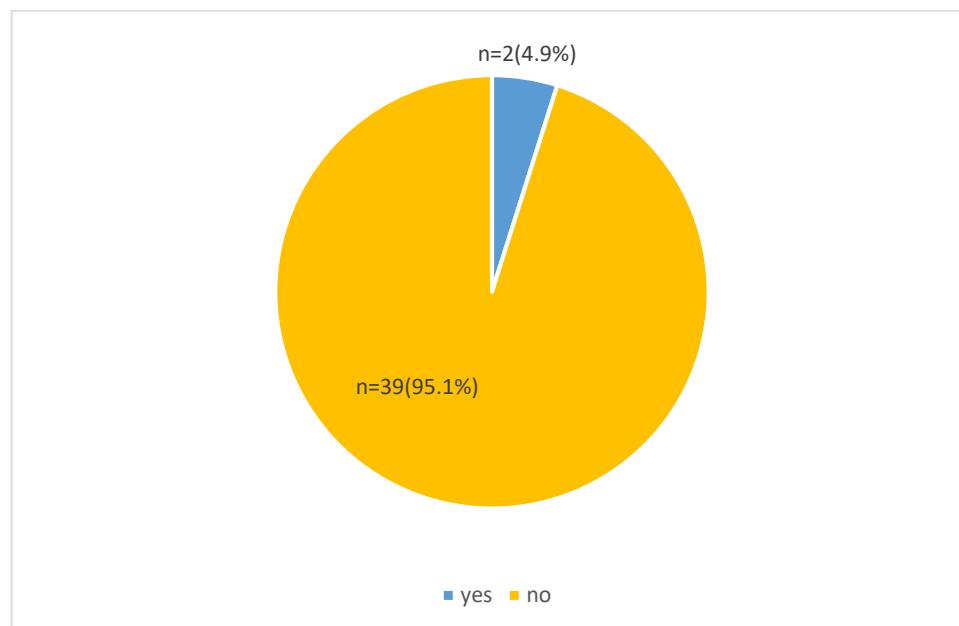


Figure 4.3: Disability on admission

4.4.6 Question 10: Indicate whether the patient had any of the following social habits

Results show that n=4 (9.8%) of the patients had a smoking habit, and n=2(4.9%) had a social habit of consuming alcohol. The smoking habit was not documented in n=8(19.5%) trial bundles whilst alcohol and unsolicited drugs were not documented in ten trial bundles n=10(24.4%). Eleven (26.8%) were minors and their social habits recorded as not applicable, as shown in table 4.3.

Table 4.3: Social habits

Social habits	yes	no	not documented	minor
Smoking	n=4(9.8%)	n=18(43.9%)	n=8(19.5%)	n=11(26.8%)
Unsolicited drugs	n=0(0%)	n=20(48.8%)	n=10(24.4%)	n=11(26.8%)
Alcohol	n=2(4.9%)	n=18(43.9%)	n=10(24.4%)	n=11(26.8%)

4.4.7 Question 11: Any underlying medical conditions on admission

The number of patients who were admitted with a medical condition is almost the same as those admitted without a medical condition as shown in figure 4.4, with n=21(51.2%) that had, and n=20(48.8%) that did not have any medical condition prior to admission.

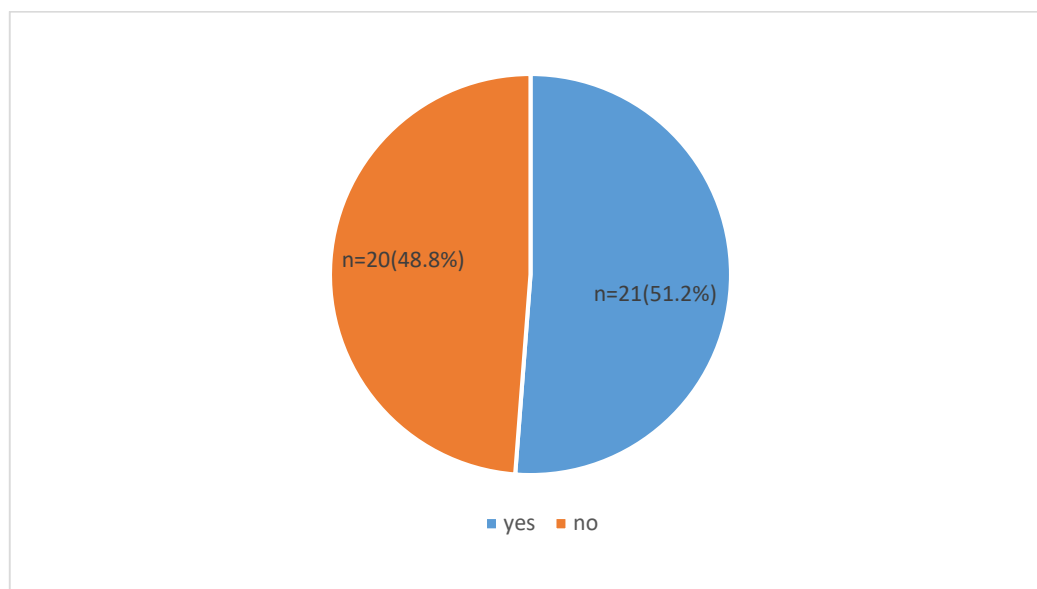


Figure 4.4: Underlying medical condition on admission

4.4.8 Question 12: Employment at the time of admission

The minor set aside, figure 4.5 reflects that $n=18(43.9\%)$ of the patients were employed, and that $n=4(9.8\%)$ were self-employed with their own businesses. Five patients $n=5(12.2\%)$ were not employed at the time of admission and three patients $n=3(7.3\%)$ were pensioners.

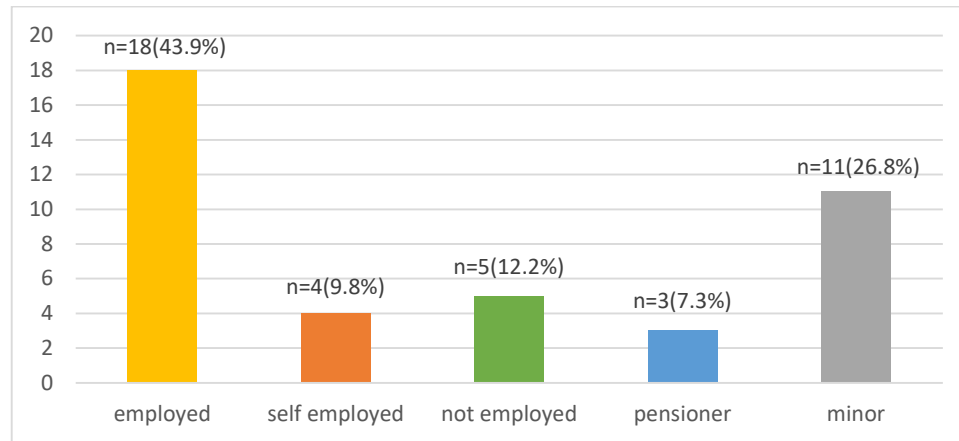


Figure 4.5: Employment at time of admission

4.5.9 Question 13: Type of employment upon admission

Results as reflected in table 4.5 show a distribution of various types of employment among the patients which included $n=9(40.1\%)$ business people, and $n=7(31.1\%)$ professional type of employment.

Table 4.4: Type of employment upon admission

	Frequency	Percent
Professional	7	31.1
Technical	3	13.6
Business	9	40.1
Administrative	2	9.0
Tradesman	1	4.5
Total	22	98.3

4.5 SECTION C: HOSPITALIZATION

Section C of the questionnaire documents the hospitalization period of the patients.

4.5.1 Question 14: Indicate whether the nursing ward notes are available to audit

Figure 4.6 reflects that only n=38(92.7%) trial bundles had the nursing ward notes available to audit.

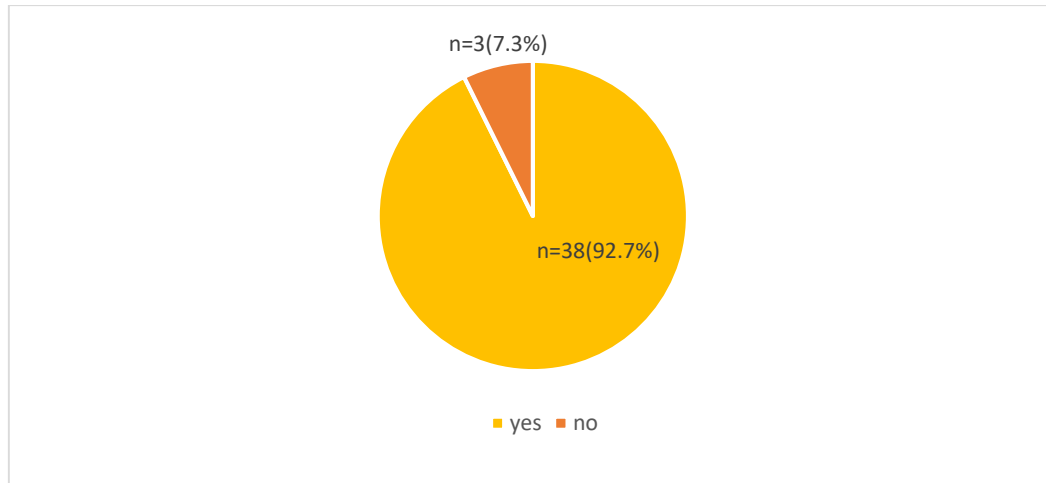


Figure 4.6: Nursing ward notes available to audit

4.5.2 Question 15: Indicate the reason for admission

Patients were admitted to the hospital for various reasons as shown in figure 4.7.

Fourteen (34.1%) patients were admitted as emergency admissions, followed by n=13(31.7%) admitted with an illness and required medical intervention. A total of twelve patients, n=12(29.3%) were admitted for elective surgery.

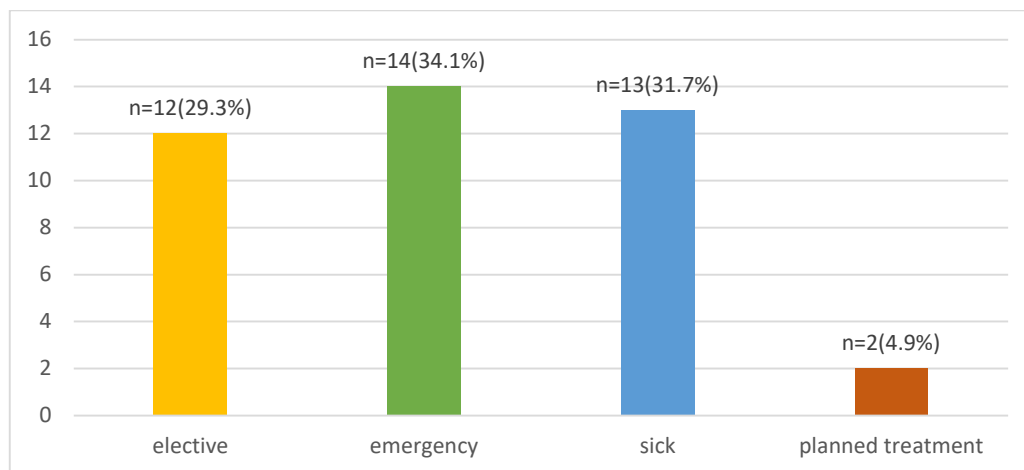


Figure 4.7: Reason for admission

4.5.3 Question 16: Indicate the type of discipline the patient was admitted to prior to the adverse event.

Table 4.5 reflects that n=9(22%) patients were admitted to the trauma discipline prior to the adverse event. Seven (17.1%) patients were admitted to the obstetrics discipline; n=5(12.2%) were admitted to general surgery.

Table 4.5: Type of discipline the patient was admitted to prior to the adverse event

Column1	Frequency	Percent
Cardiology	3	7.3
Gynaecology	2	4.9
Medical	1	2.4
Obstetrics	7	17.1
Neonatology	4	9.8
Nephrology	2	4.9
Neurosurgery	3	7.3
Orthopaedics	1	2.4
Paediatrics	4	9.8
Trauma	9	22
General surgery	5	12.1
Total	41	100

4.5.4 Question 17: Indicate the type of ward or unit to which the patient was admitted to before the adverse event.

The largest number of patients n=13(31.7%) were admitted to an emergency ward or casualty as shown in figure 4.8. Furthermore n=9(22%) patients were admitted to a general ward and n=7(17.1%) were taken to the labour ward upon admission.

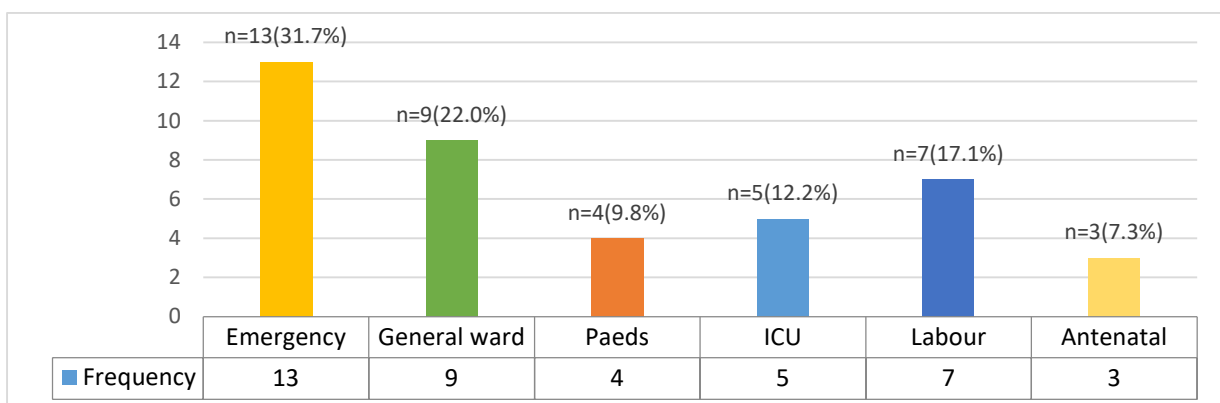


Figure 4.8: Type of ward to which the patient was admitted before the adverse event

4.5.5 Question 18: Indicate the status of the initial assessment of the patient, including the foetus where applicable.

Figure 4.9 shows that $n=13$ (31.7%) of the initial assessments were incomplete and two initial assessment, $n=2$ (4.9%) was not documented.

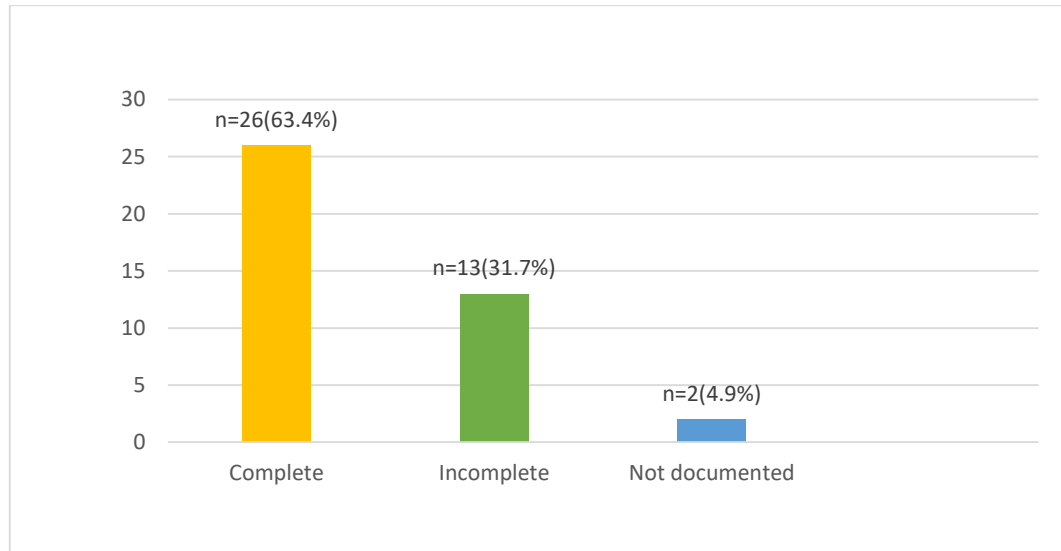


Figure 4. 9: Status of the initial assessment

4.6.7 Questions 19: Indicate the status of the care plan of the patient.

Twenty-eight (68.3%) of the care plans were complete. However $n=4$ (9.8%) were incomplete and $n=9$ (21.9%) were not documented.

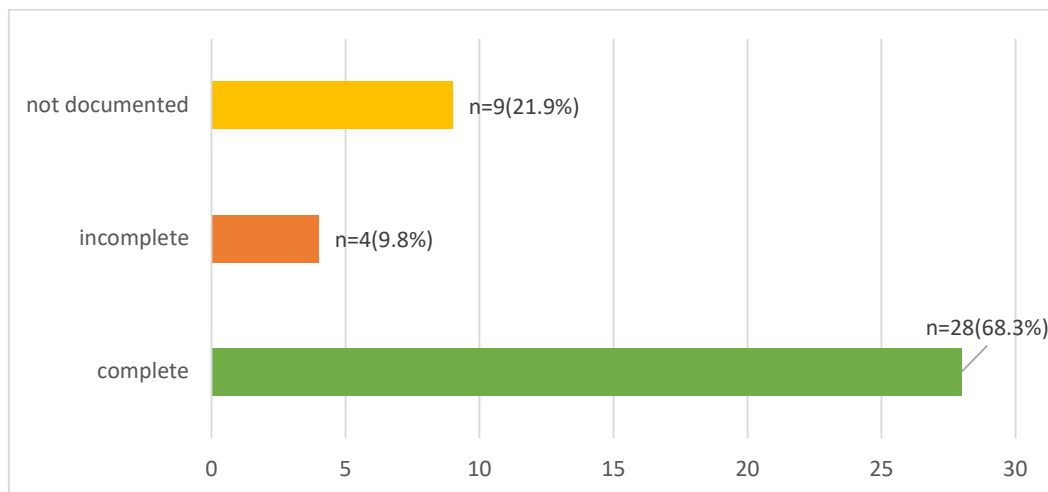


Figure 4.10: Status of the care plan

4.6.8 Question 20: Indicate whether the care plan was implemented.

Twenty-nine (70.8%) of the care plans were implemented. There is an equal distribution of care plans not done and not implemented, $n=6$ (14.6%) respectively.

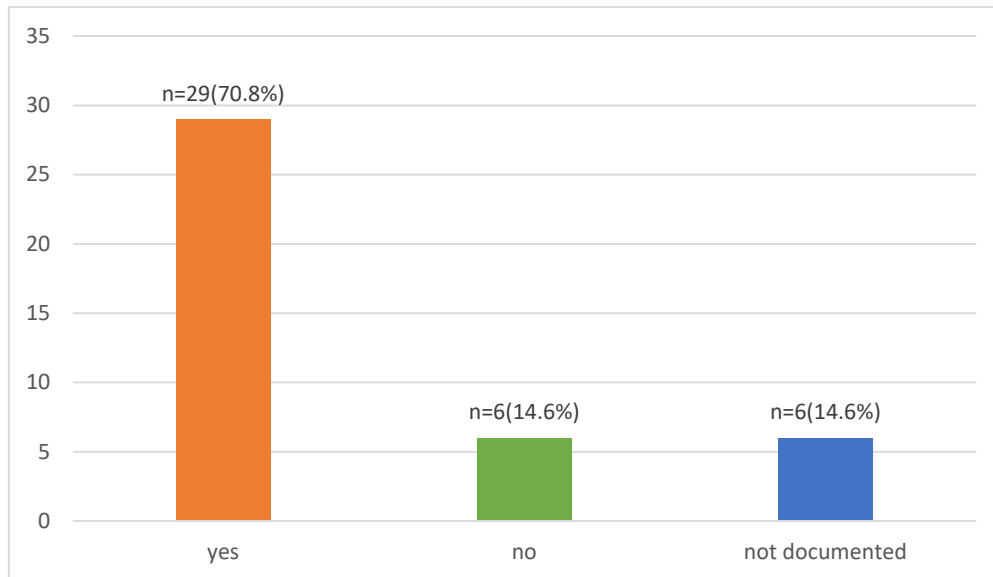


Figure 4.11: Implementation of the care plan

4.6.9 Question 21: Indicate whether special care plans were required

Figure 4.12 reflects that $n=28$ (68.3%) required special care plans of which $n=2$ (4.9%) were not documented.

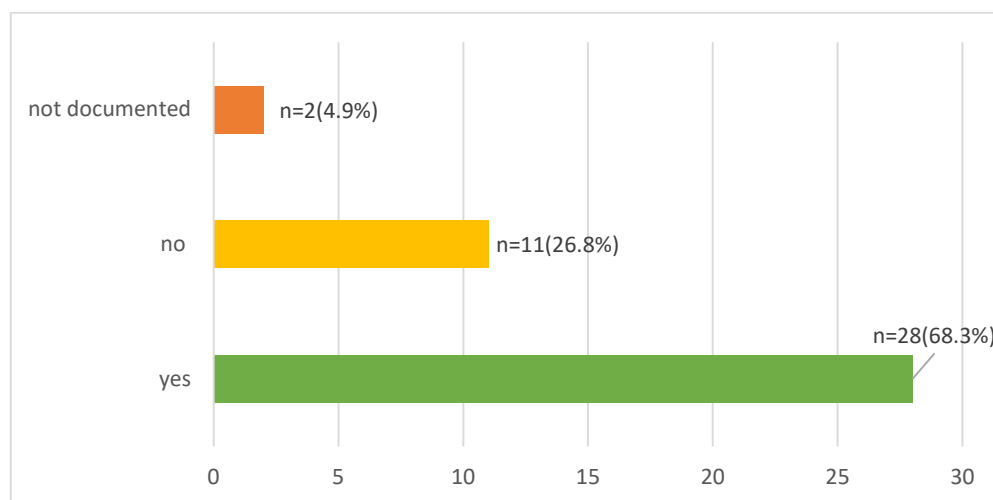


Figure 4.12 Special care plans required

4.6.10 Question 22: Indicate the status of the special care plan of the patient

As shown in figure 4.13 $n=8(19.5\%)$ special care plans were incomplete and a total of $n=9(21.9\%)$ were not documented at all.

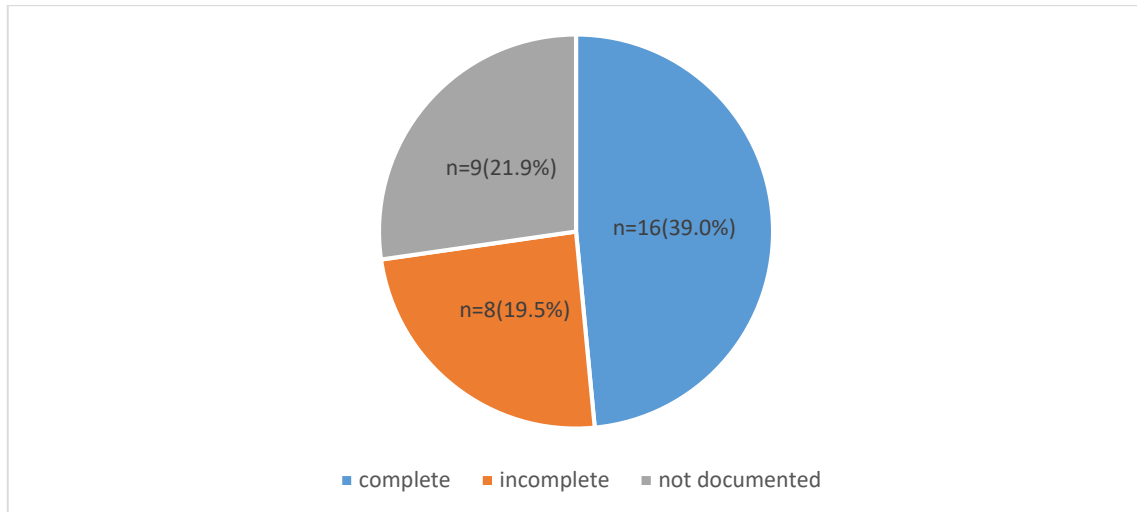


Figure 4.13: Status of special care plan

4.6.11 Question 23: Indicate whether the special care plan was implemented

Figure 4.14 reflects that thirteen, $n=13(31.7\%)$ special care plans, although drawn up, were not implemented.

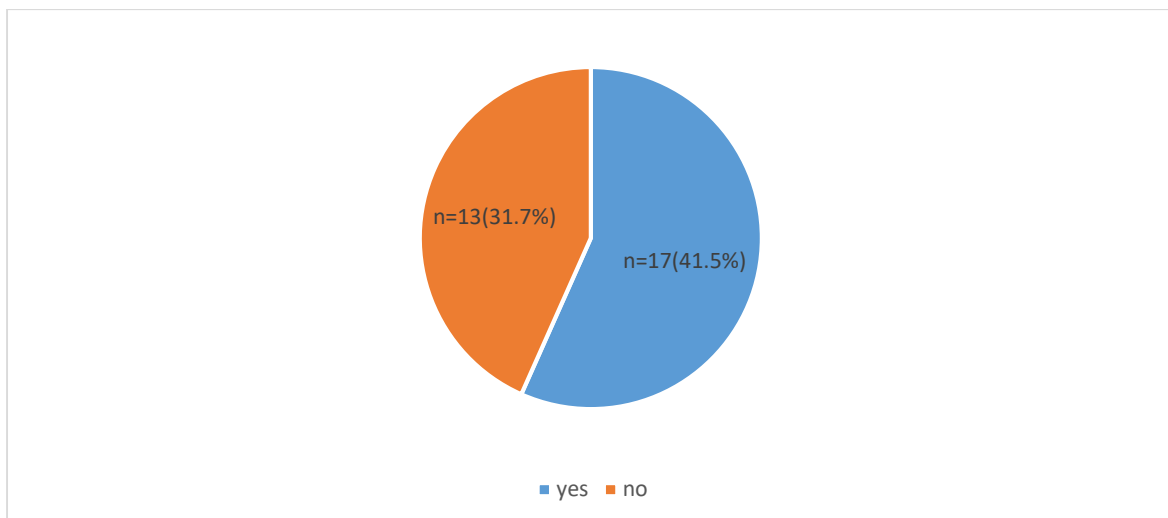


Figure 4.14: Implementation of special care plan

4.6.9 Question 24: Indicate whether any of the following vital signs were monitored

Figure 4.15 shows n=33(78%) of the patients required blood pressure monitoring, and n=6(19%) reflected incomplete monitoring, and one was not documented at all.

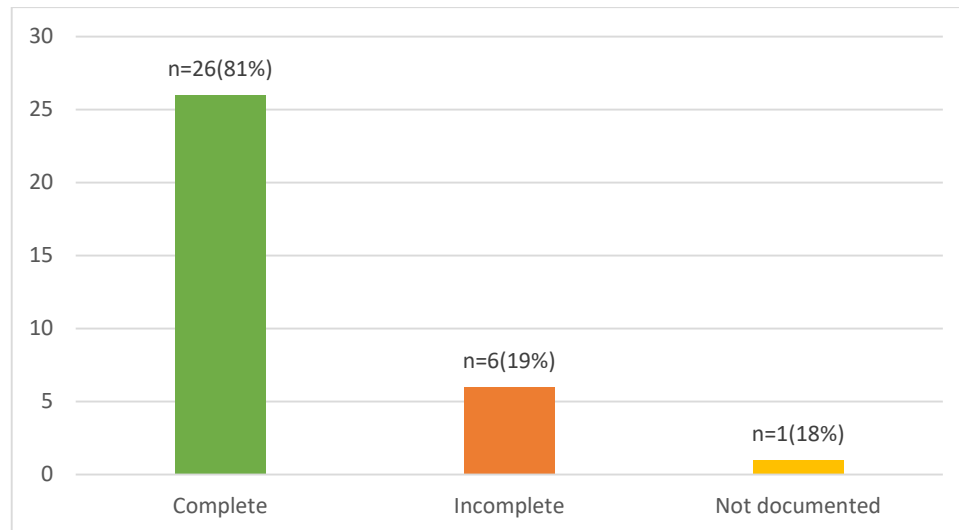


Figure 4.15: Blood pressure monitoring

Figure 4.16 shows from all the patients that required pulse monitoring, n=9(22%) had incomplete monitoring.

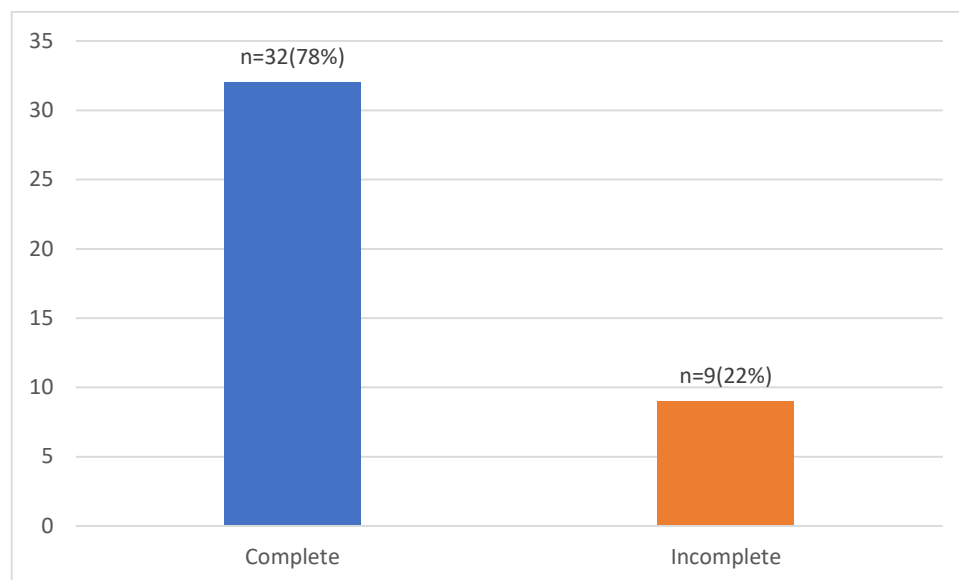


Figure 4.16: Pulse Monitoring

Figure 4.17 shows that of the $n=13$ (31%) patients that required foot pulses monitoring, $n=6$ (46%) had incomplete monitoring.

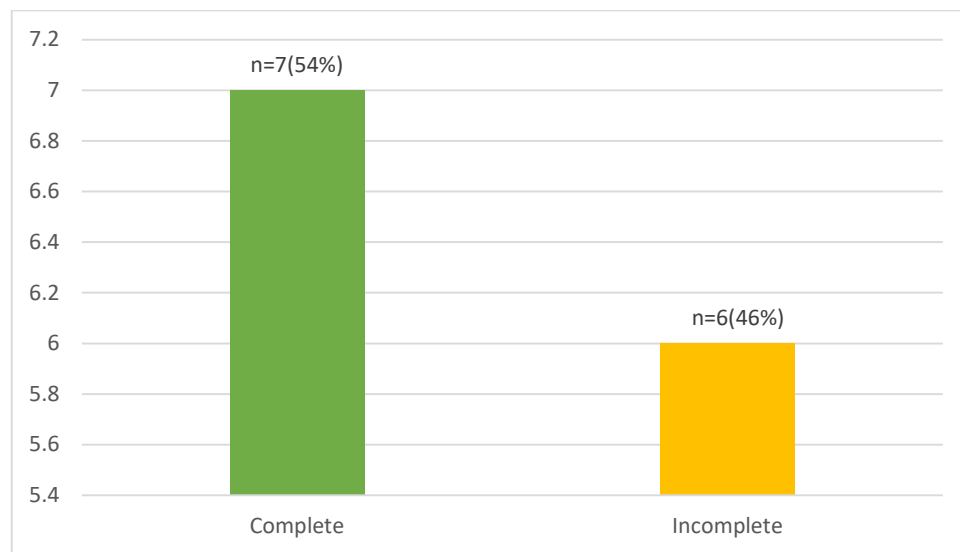


Figure 4.17: Foot pulses monitoring

Figure 4.18 shows that of the $n=4$ (9.8%) of the patients that required foetal monitoring, two patients' records were incomplete regarding the procedure.

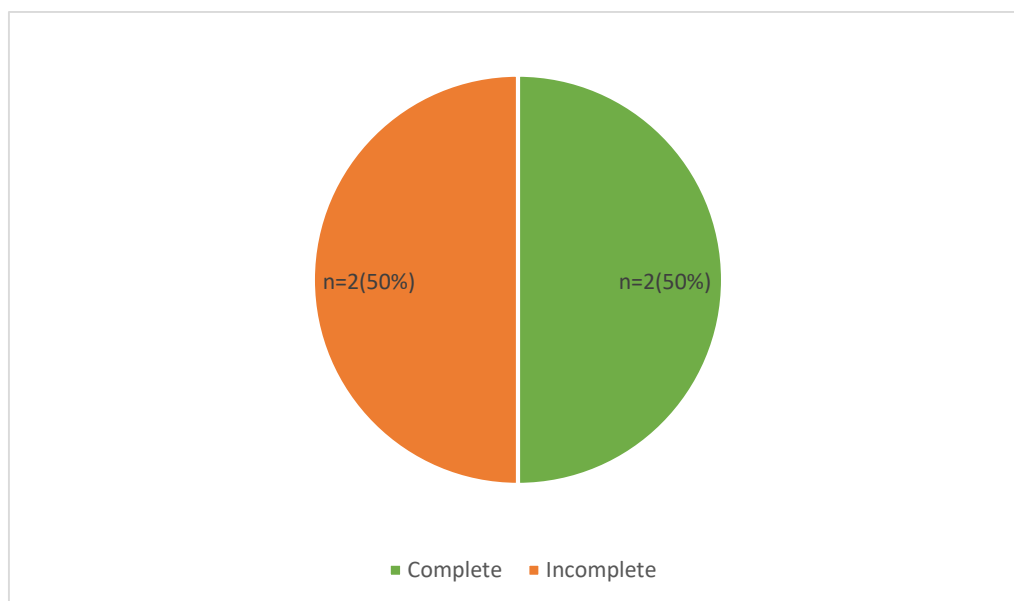


Figure 4.18: Foetal monitoring

Figure 4.19 shows that of all the patients, $n=41$ (100%) required respiratory monitoring of which $n=8$ (19.5%) the respiratory monitoring was found to be incomplete, and one had no documentation regarding the issue.

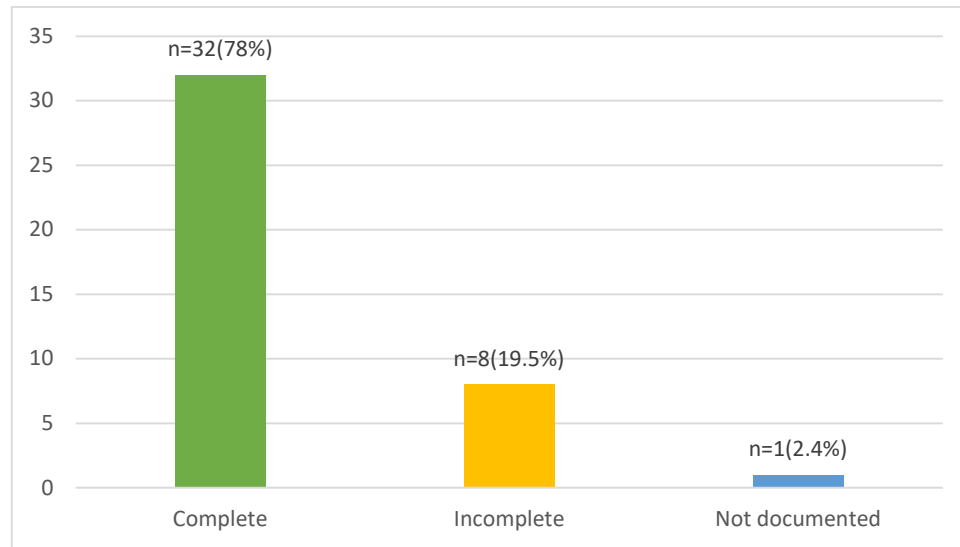


Figure 4.19: Respiration monitoring

Figure 4.20 shows that $n=40$ (97.5%) patients required intake and output monitoring. Ten (25%) records were incomplete and $n=1$ (2.5%) did not have the intake and output monitoring documented at all.

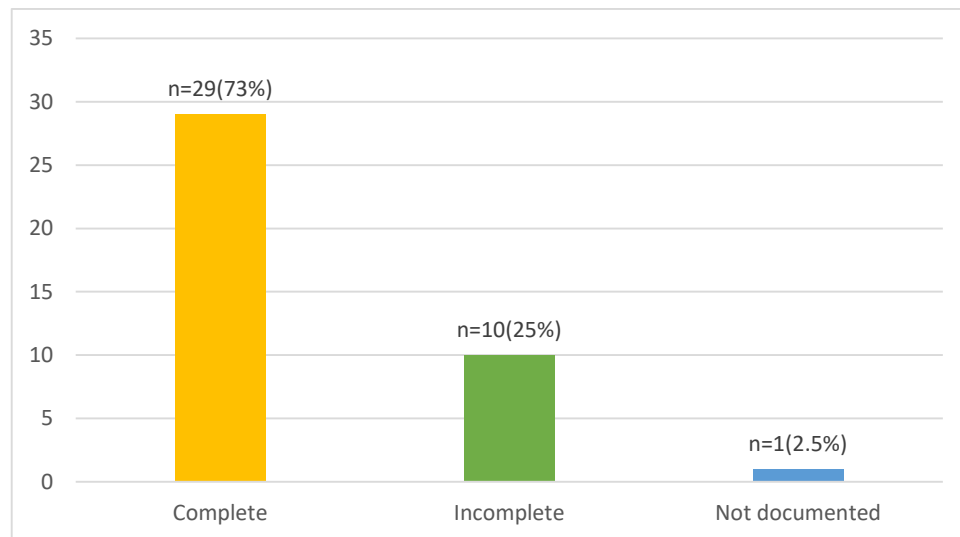


Figure 4.20: Intake and output monitoring

Figure 4.21 shows that only $n=17$ (41.5%) patients had complete weight monitoring. Of the rest $n=5$ (12.2%) were incomplete and $n=19$ (46.3%) were not documented at all.

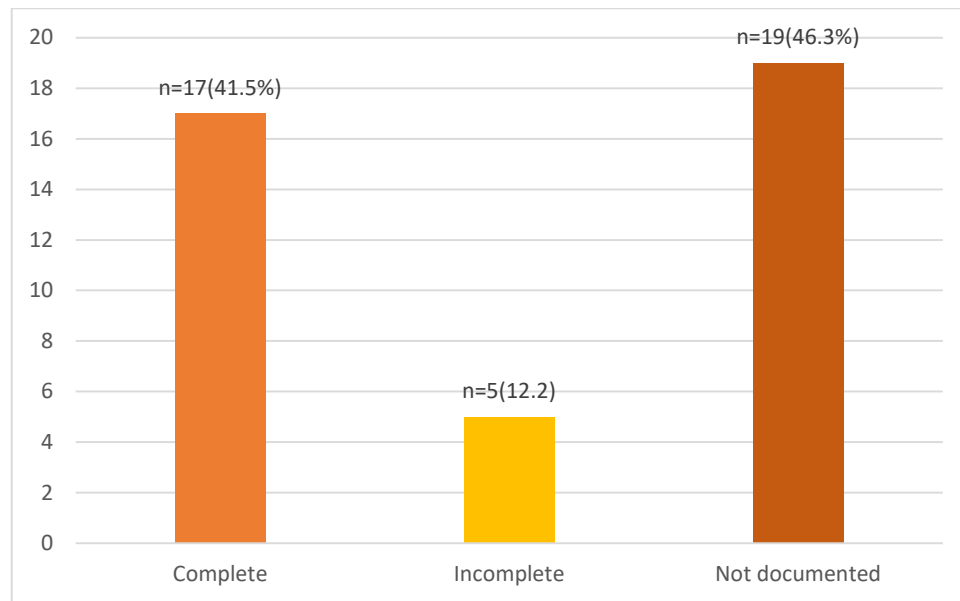


Figure 4.21: Weight monitoring

Figure 4.22 shows that from $n=28$ (68.3%) patients who required neurological observations, $n=9$ (32.1%) had incomplete monitoring of this function, with one that did not have any documentation at all.

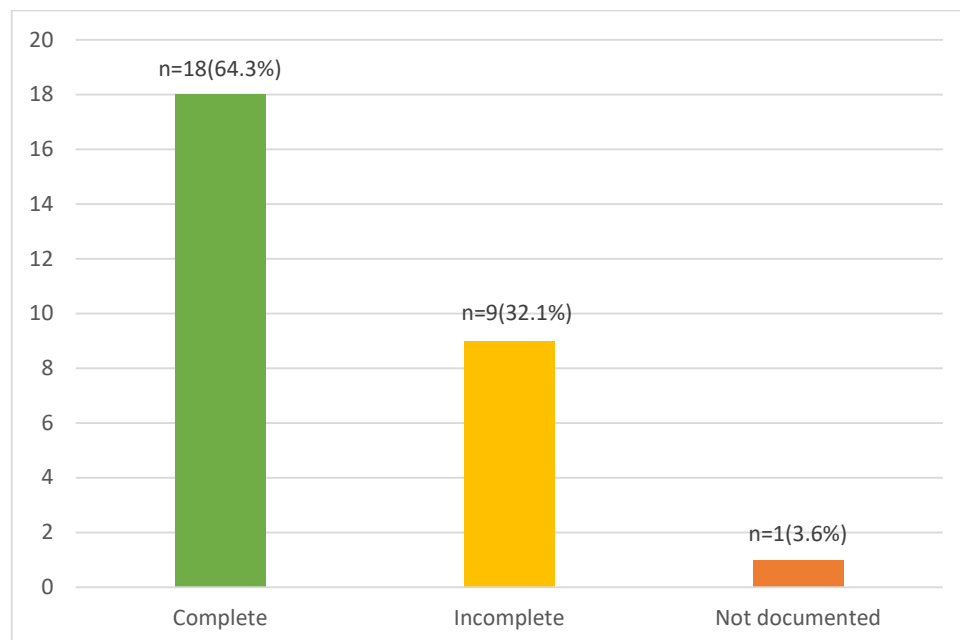


Figure 4.22: Neurological observations

Figure 4.23 shows that of the $n=10(50\%)$ patients that required post-spinal surgery observations, $n=4(40\%)$ reflected incomplete monitoring of this function, and one had nothing documented.

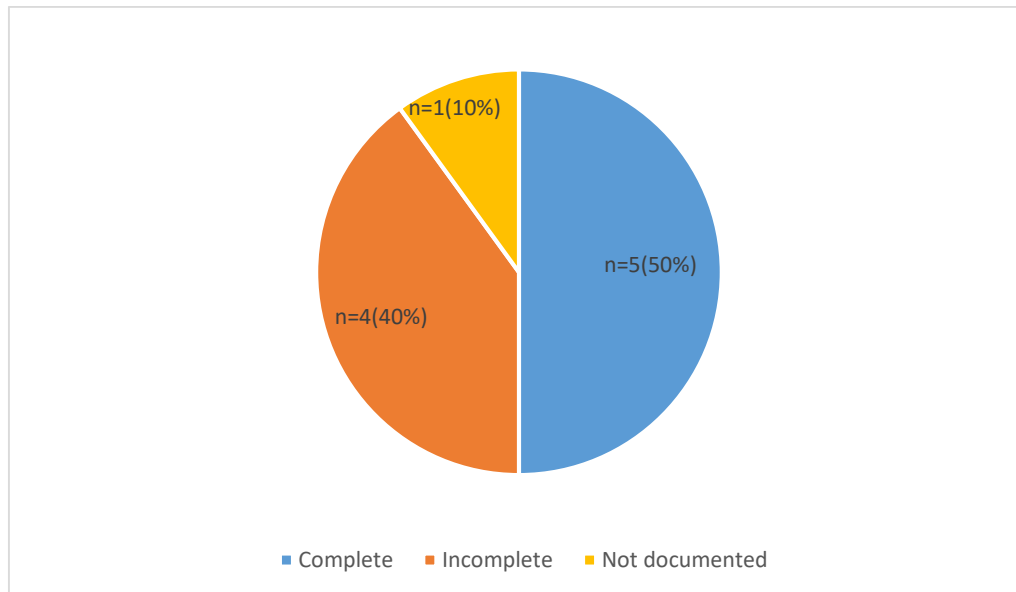


Figure 4.23: Post-spinal surgery observations

Figure 4.24 shows that from a total of $n=24(58.5\%)$ patients that required the mental status monitoring, seven trial bundles $n=7(29.2\%)$ demonstrated incomplete monitoring, with one that had none documented.

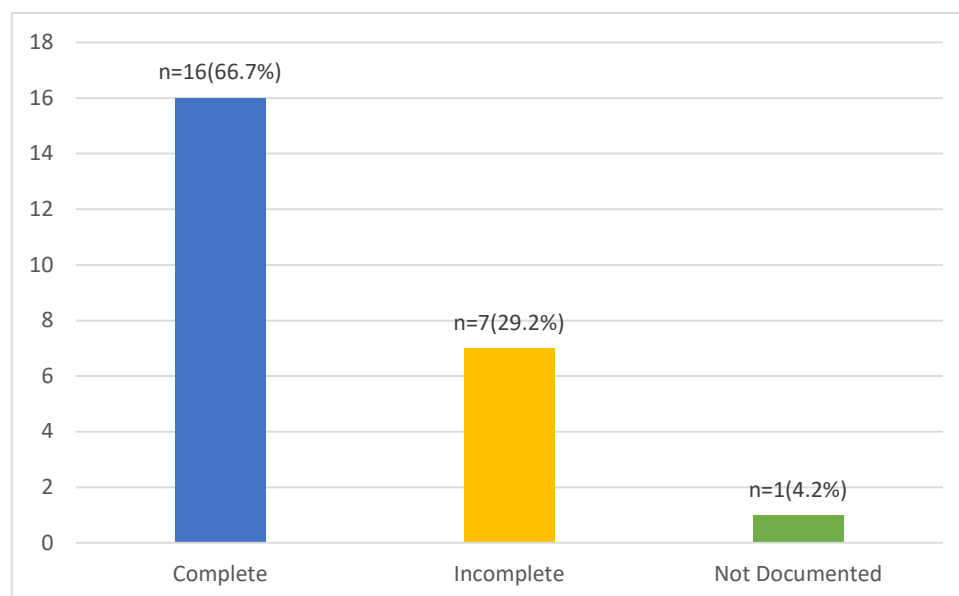


Figure 4.24: Mental status monitoring

Figure 4.25 shows of the n=25(60.9%) patients that required electrocardiography (ECG) monitoring of the patients, n=6(24%) reflected incomplete monitoring and one had no monitoring documented at all.

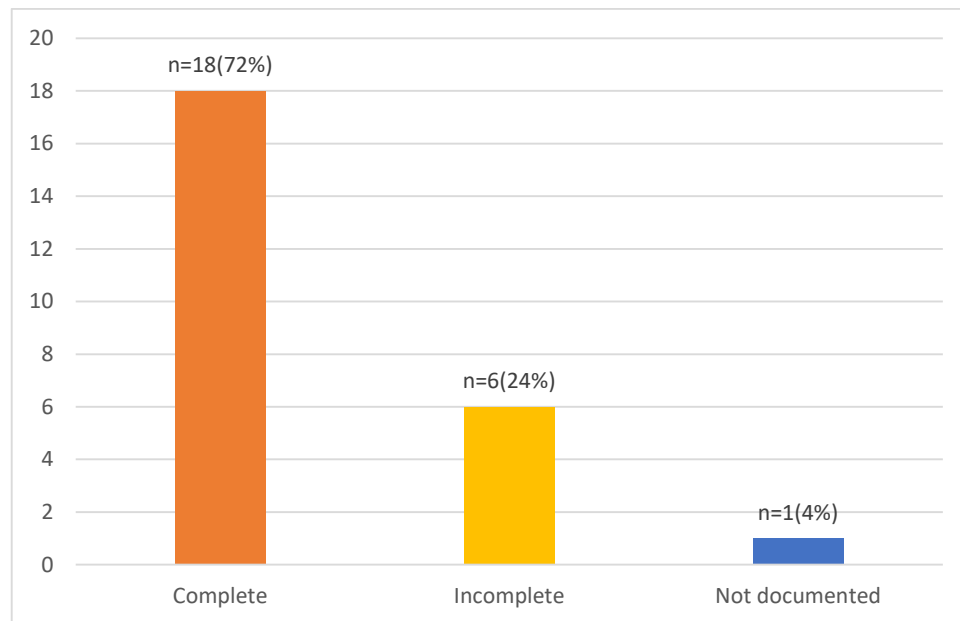


Figure 4.25: Continuous ECG monitoring

Of the thirty-seven (90%) patients that required continuous oxygen monitoring, n=9(24.3%) had incomplete oxygen monitoring, as reflected in figure 4.26.

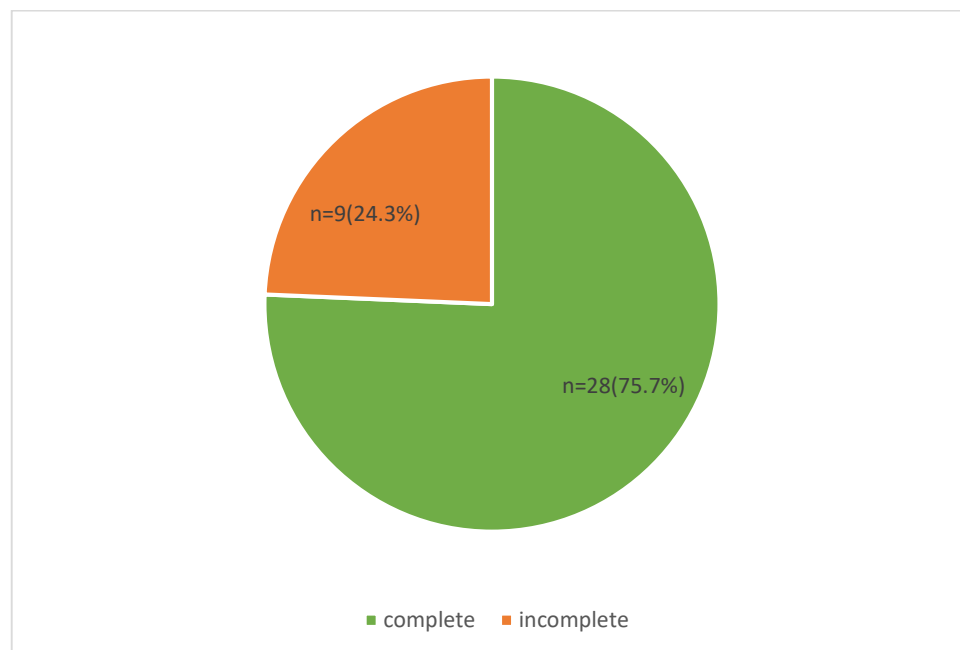


Figure 4.26: Continuous oxygen monitoring

4.6.10 Questions 25: Indicate whether the following diagnostic tests were done pre-adverse event

Table 4.6 reflects that of the n=40(97.6%) patients that required diagnostic tests, n=7(17.5%) patients' diagnostic tests were not documented pre-adverse event.

Table 4.6: Tests done pre-adverse event

	Frequency	Percentage
Haemoglucotest	33	82.5
Haemoglobin	33	82.5
Urine tests	15	37.5
Urea and electrolytes	33	82.5
Blood gases	33	82.5
Full blood count	33	82.5
Liver functions	33	82.5

4.6.11 Questions 26: Were the results of the tests interpreted?

Figure 4.27 reflects that the interpretation of the diagnostic tests of n=9(22%) patients were not documented and n=8(19.5%) were incorrectly interpreted.

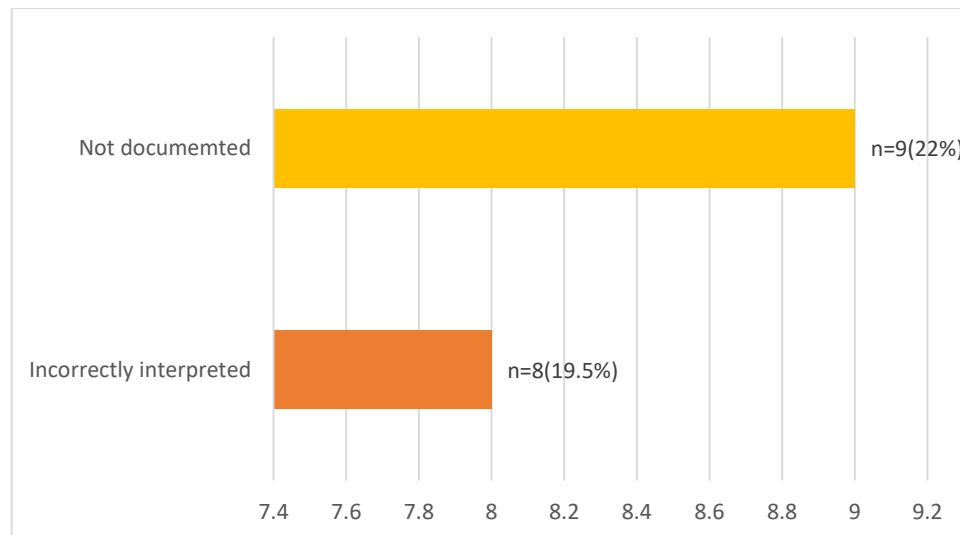


Figure 4.27: Interpretation of diagnostic test results

4.6.12 Question 27: Were the results reported to the doctor?

The diagnostic test results of n=36 (87.8%) patients had to be reported to the doctor, but n=4(11.1%) of the patients' results were not reported as shown in figure 4.28.

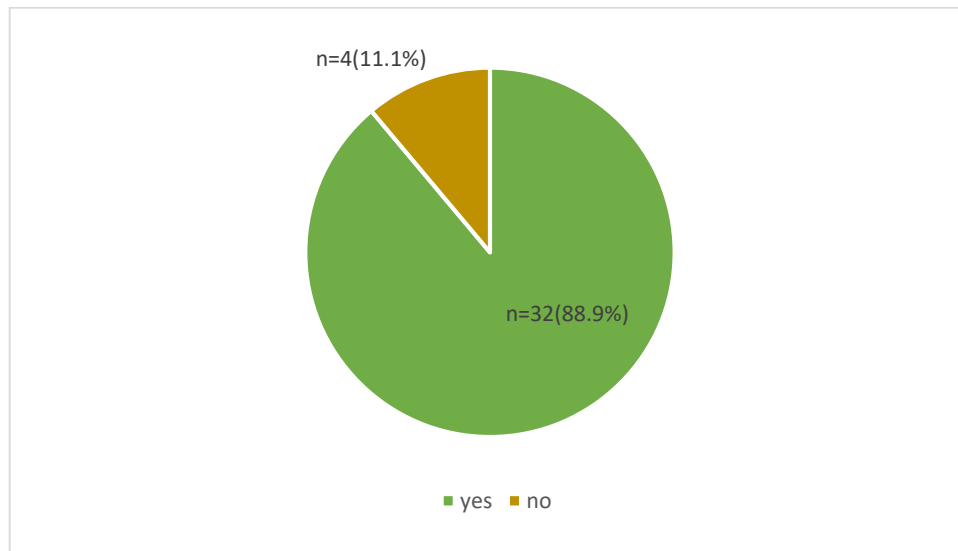


Figure 4.28: Diagnostic test results reported to the doctor

4.6.13: Question 28: Indicate whether any action was taken based on the results

Thirty-five (85.4%) patients required action to have been taken based on the diagnostic test results, but no such action was taken in n=19(54.3%) of the patients as reflected in figure 4.29.

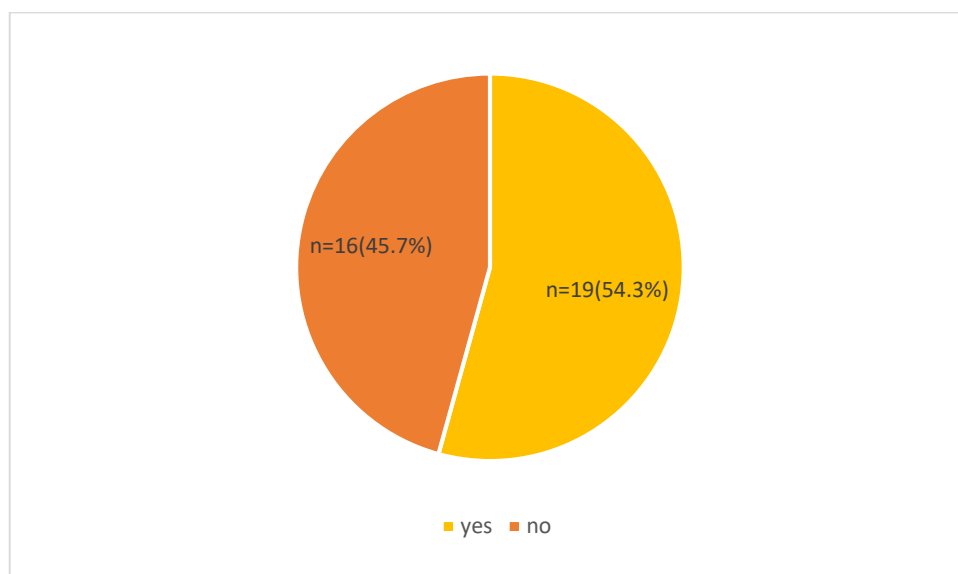


Figure 4.29: Action taken based on the results

4.6.14 Question 29: Indicate the status of the pre-operative assessment for surgery.

Twenty-three (56.1%) patients required pre-operative assessment for surgery of which n=7(30.4%) were incomplete and n=5(21.7%) did not have their pre-operative assessment for surgery documented, as reflected in figure 4.30.

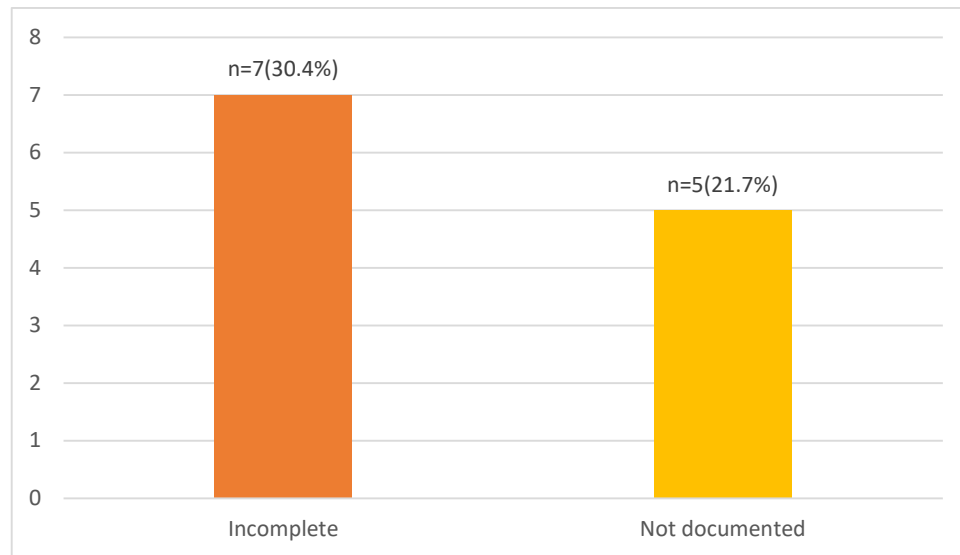


Figure 4.30: Pre-operative assessment done

4.6.15 Question 30: Indicate whether the treatment/ technique/ management as prescribed was given

Figure 4.31 shows that in n=20(48.8%) patients the management was not given as prescribed.

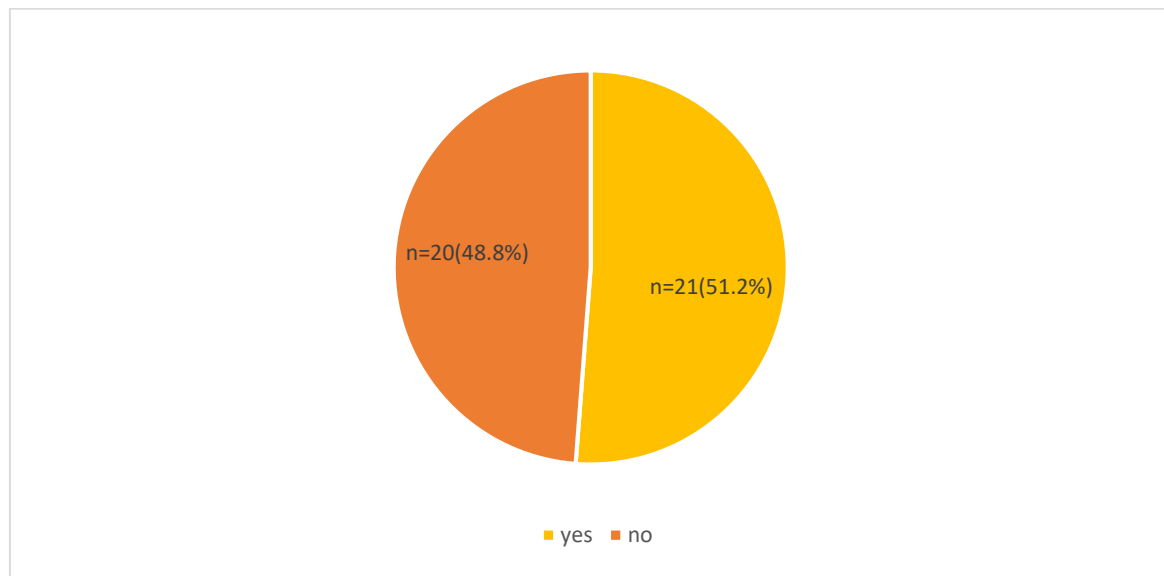


Figure 4.31: Management was given as prescribed

4.6.16 Question 31: Do the patient's "progress report" reflect the following about the patient?

Initial report: Nine (22%) patients' initial report were incomplete and n=1 (2.4%) reflected an initial report that was not documented.

Progress report: Nineteen (46.3%) patients' progress report were incomplete and n=1(2.4%) not documented.

Clinical manifestations not responded to: The response to clinical manifestations were incomplete in n=35 (85.4%) of the patients and n=3(7.3%) were not documented.

Interim report: Twenty-one (51.2%) of the patients' interim reports were incomplete and n=1(2.4%) not documented.

Reports to the doctor: Twenty (48.8%) patients' reports to the doctor were incomplete.

Discharge report: The majority of the patients n=32(78%) had no discharge reports documented and n=9(22%) were incomplete.

Table 4.7: Reflection of patient's progress report

	Complete	Incomplete	Not documented
Initial report	n=31(75.6%)	n=9(22%)	n=1(2.4%)
Progress report	n=20(48.8%)	n=19(46.3%)	n=1(2.4%)
Clinical manifestations not responded to	n=3(7.3%)	n=35(85.4%)	n=3(7.3%)
Interim report	n=19(46.3%)	n=21(51.2%)	n=1(2.4%)
Reports to the doctor	n=19(46.3%)	n=20(48.8%)	n=2(4.9%)
Discharge report	n=0(0%)	n=9(22%)	n=2(4.9%)

4.6.17 Question 32: If the patient was discharged, indicate whether specific patient education was given.

Thirty-eight (100%) patients required specific patient education, but no patient education was given to any patient.

4.7 SECTION D: OPERATION ROOM

Section D reflects the operating room details of the patients, as applicable in each trial bundle.

4.7.1 Questions 33: Indicate, where applicable, whether the following protocols in the operating room were adhered to:

Table 4.8 shows n=13 patients required operating protocols to be adhered to, however in one there was a failure to adhere to the swab count protocol and in another a failure towards specimen control.

Table 4.8: Operating room protocols

	Yes	No
Swab count	12	1
IPC measure	13	0
Instrument control	13	0
Specimen control	12	1
Use of diathermia	13	0
Surgical pause/ time out	13	0

4.8 SECTION E: ADVERSE EVENT(S)

Section E of the questionnaire documents the details of each adverse event.

4.8.1 Question 34: Indicate the environment where the adverse event(s) occurred.

Seven (17.1%) adverse events occurred in the labour ward, n=6(14.6%) each in the Intensive Care Unit (ICU), n=6(14.6%) in the general ward and n=6(14.6%) in the operating room as reflected in table 4.9.

Table 4.9: Environment where adverse event occurred

	Frequency	Percentage
General ward	6	14.6
ICU	6	14.6
Operating room	6	14.6
Paediatrics	4	9.8
Neonatology	5	12.2
Casualty/ Trauma	3	7.3
Labour ward	7	17.1
Psychiatry	0	0
Other: High Care	2	4.9
Other: Post-natal	1	2.4
Other: Renal Transplant Clinic	1	2.4

4.8.2 Question 35: Describe the adverse event(s)

Due to the sensitivity of the data collected, only a brief description of the adverse event can be given. This ensures that there would be no link between the court case and all the parties involved.

General ward:

- Following cardio-thoracic surgery, central venous pressure line in neck removed and resulted in hemiplegia due to air in sub-arachnoid space.
- After a laparoscopic procedure, patient experienced hypothermia and hypotension due to intra-abdominal bleeding.
- Following a sigmoid colectomy procedure, an injection of Morphine, Zofran and Methylnaltrexonebromide was given within one hour and resulted in severe hypoxic brain damage.
- Upon admission for drainage of splenic abscess, patient experienced severe pain in left flank. Intramuscular injection in gluteus resulted in permanent sciatic nerve damage.
- Following admission for bilateral rib fractures, the management of the patient between two hospitals resulted in the patient sustaining various pressure sores and rendered the patient a quadriplegic.
- After being admitted for hypoglycaemic coma, patient fell out of bed and sustained fracture of right hip; resulting in hip surgery.

Paediatric ward:

- An intravenous infusion was allowed to extravasate into the soft tissue of a child's hand and wrist, resulting in swelling and blistering; requiring a skin graft.
- A minor admitted with diarrhoea and dehydration, intravenous infusion resulted in swollen hand requiring skin graft.
- Minor child sustained severe hypoxic-ischaemic encephalopathy as a consequence of severe dehydration.
- Minor child admitted for pneumonia, was treated with endotracheal tube incorrectly positioned, resulting in cerebral palsy due to oxygen deprivation.

Labour ward:

- Baby diagnosed with cerebral palsy secondary to birth asphyxia, due to mismanagement of labour process.

- Misdiagnosis of 3rd or 4th degree perineal tear as a second degree tear after a normal vaginal delivery with an episiotomy, resulted in sphincters being destroyed.
- After admission for pre-eclampsia, patient given intramuscular injection for pain control. Resulting in pain at injection site, being diagnosed with cellulitis in right gluteal area.
- Admitted to community health centre for latent phase of labour and then transferred to hospital for prolonged second stage. Following failed attempt of MacRobert's manoeuvre and increased waiting time in labour ward, foetus born with cerebral palsy.
- Complaints of abdominal pains were medically mismanaged and resulted in fetal distress at 32 weeks gestation; foetus did not survive the severe hypoxia.
- Baby diagnosed with cerebral palsy secondary to birth asphyxia, due to mismanagement of labour process.
- Following caesarean section, patient discharged with symptoms of pyrexia and tachycardia; admitted the same day with small bowel perforation and abdominal sepsis.

Neonatology unit:

- A pulse oximeter was placed on a neonate's foot and not adequately monitored for pressure care, resulting in necrosis and amputation of the right small toe.
- An arterial line was inserted and as a result, the child developed gangrene and had to undergo an amputation.
- Minor prematurely discharged whilst being severely dehydrated due to diarrhoea, resulting in permanent brain damage and left sided spastic hemiplegia.
- Premature baby admitted to neonatology unit ventilated then received continuous oxygen therapy, resulting in diagnosis of per ventricular leukomalacia.
- Baby readmitted to hospital with dehydration and pyrexia following birth. Resulting in diagnosis of bilirubin-induced neurological dysfunction.

Intensive Care Unit:

- After being hospitalized for malaria, patient developed pressure sores in gluteal area. Resulting in permanent damage of sciatic nerve and permanent loss of function of lower limbs.
- Admitted for coronary artery bypass grafting procedure, resulted in compromised circulation and above knee amputation.
- Following admission for gastric surgery, patient acquired klebsiella pneumonia and various viruses within the clinical environment.

- After a spinal operation, the patient developed cauda equina syndrome due to insufficient drainage and ongoing haemorrhage in the operation site.
- Poor circulation monitoring in lower limbs following surgical procedure, resulted in permanent damage to nerves.
- Incorrect management following a spinal decompression and fusion procedure, resulted in paralysis.

Operating room:

- A patient presenting with abdominal pain was diagnosed incorrectly, resulting in a colostomy.
- A patient admitted for orthopaedic surgery suffered a cardiac arrest in theatre, resulting in ischaemic brain damage.
- The patient consented to decompression of L2/ L3 spinal procedure, the surgeon performed decompression of L3/ L4.
- A patient injected with Perlane into nasolabial folds, resulting in permanent damage to infraorbital nerve on left side of face.
- A patient admitted for exploratory laparotomy for small bowel obstruction, resulted in abdominal swab left inside after procedure.
- The patient died in theatre due to gunshot to right flank in the abdomen, as a result of inadequate vascular repair by the surgeon.

High care:

- After laparoscopy for gastrointestinal obstruction, developed pneumonia and kept in high care. Intramuscular injection in right gluteus resulted in nerve ischiadicus.
- Following discharge after a caesarean section, with signs of pyrexia and tachycardia, the patient admitted a day later with severe sepsis resulting in septic shock and death.

Post-natal:

- Following a caesarean section, intramuscular injection on lateral aspect of left thigh formed a hard lump, resulting in fat necrosis.

Casualty/ Trauma:

- Patient seeks emergency care for bee sting on left side of neck and presenting with allergic reaction; intravenous medication administered results in thrombophlebitis.
- Incorrect assessment of a wound in the forearm, resulted in a badly scarred and mutilated arm due to an iatrogenic infection and no homecare instructions upon discharge.
- Amputation of leg following gunshot, due to delay in surgical treatment.

Renal transplant clinic:

- After renal transplant for end-stage renal failure, oral medication Ketaconazole omitted from prescription chart and not dispensed by pharmacy; resulting in body rejecting the kidney.

4.8.3 Question 36: Indicate the patient outcome(s) as a result of the adverse event.

Figure 4.32 shows that n=20(48.8%) of the patients required additional surgery as a result of the adverse event, the majority, n=38(92.7%) of the patients experienced their quality of life negatively affected and n=3(7.3%) patients died due to the adverse event.

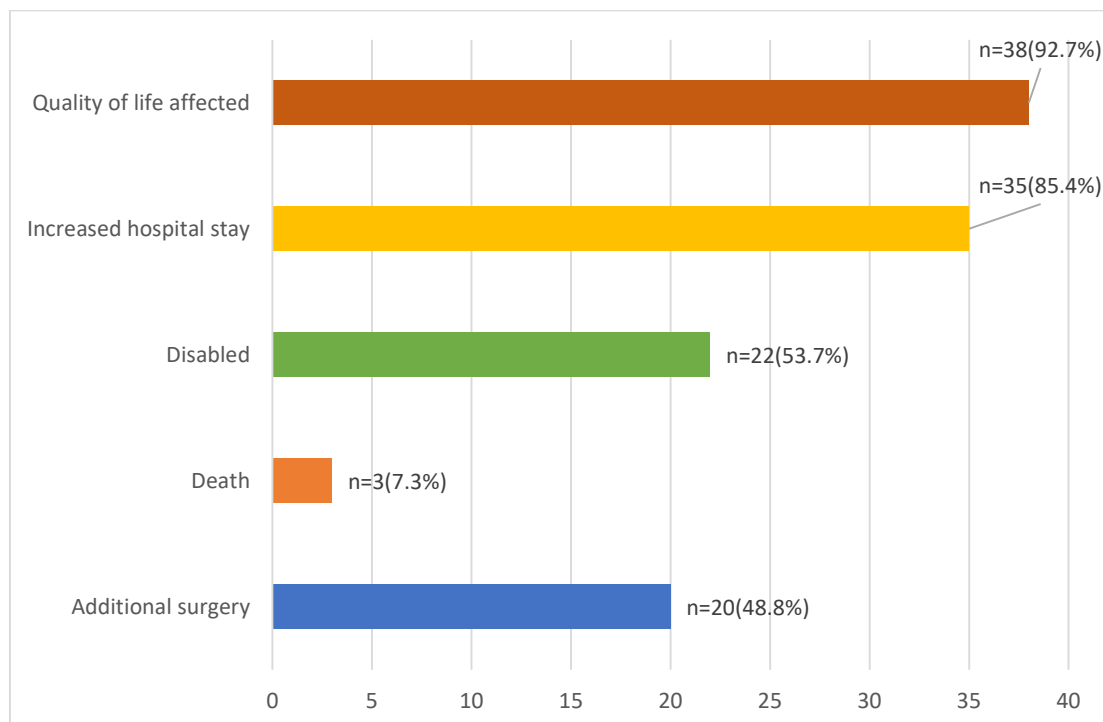


Figure 4.32: Patient outcome as a result of the adverse event

4.8.4 Question 37: Healthcare profession(s) or non-healthcare professional responsible for adverse event.

Seventeen (41.5%) of the trial bundles reflected that only the nursing profession was responsible for the adverse event, while both medical and nursing were responsible for n=12(29.3%) of the adverse events as reflected in figure 4.33.

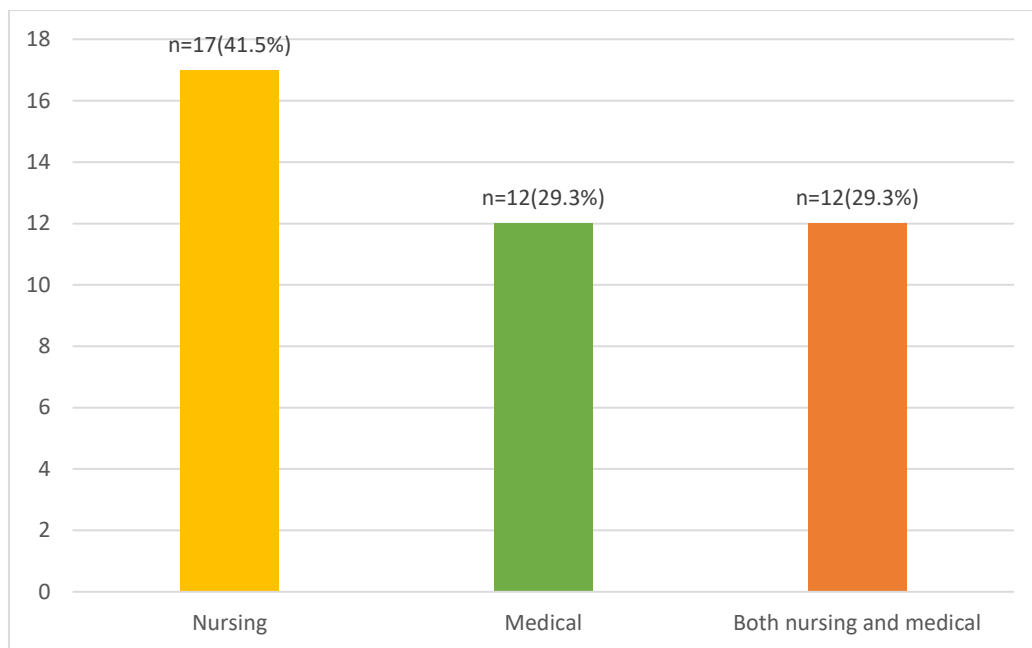


Figure 4.33: Health profession(s) responsible for the adverse event

4.8.5 Question 38: Indicate the category or categories of nurses involved in the adverse event.

Figure 4.34 reflected multiple categories of the nursing profession who were involved in an adverse event. Twenty-nine (70.7%) trial bundles reflected the professional nurse as the primary category involved in the adverse event.

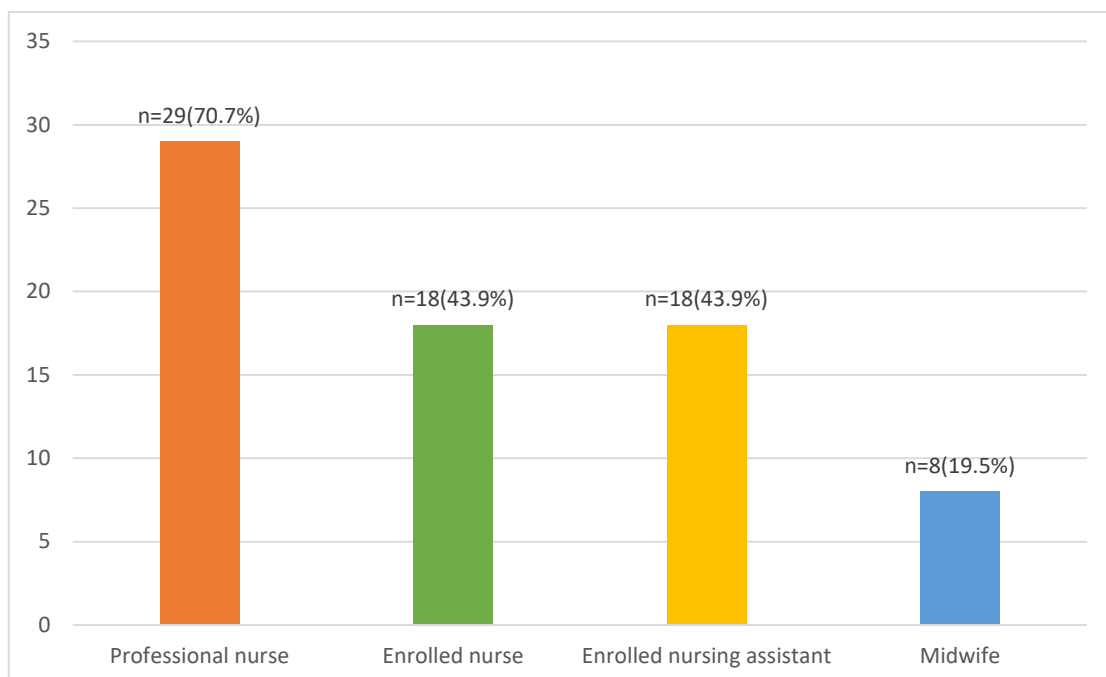


Figure 4.34: Indicate the categories of nurses involved in the adverse event

4.9 SECTION F: PRINCIPLE INCIDENT TYPE, SEVERITY OF ADVERSE EVENT AND FACTORS CONTRIBUTING TO THE ADVERSE EVENT

Section F of the questionnaire reflected the severity and factors contributing to each trial bundle.

4.9.1 Question 39: Indicate the adverse event by Principle Incident Type

Figure 4.35 reflected clinical management as the principle incident type resulting in the adverse event, $n=41(100\%)$. Nine trial bundles $n=9(22\%)$ reflected human behaviour problems.

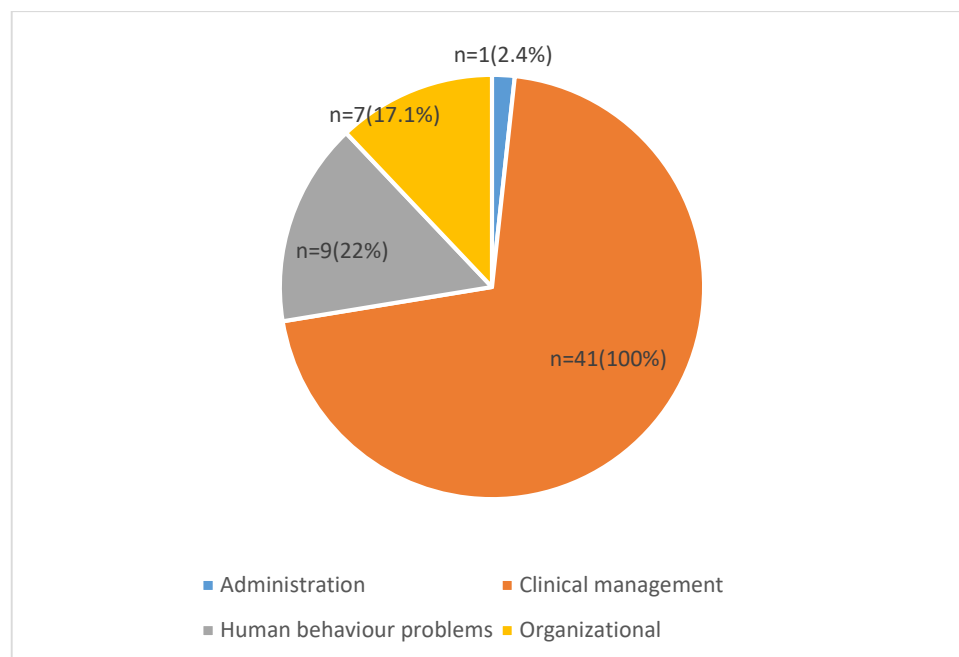


Figure 4.35: Adverse event by Principle Incident type

4.9.2 Question 40: Indicate the severity of the adverse event according to the Safety Assessment Code Matrix (SAC).

Figure 4.36 indicates that $n=19(46.3\%)$ of adverse events were classified as extreme; $n=15(36.6\%)$ were classified as major.

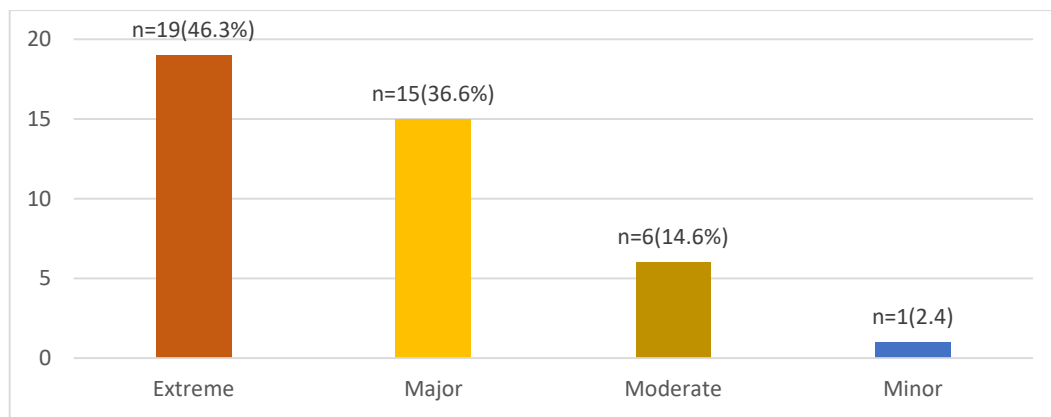


Figure 4.36: Adverse event according to the SAC Matrix

4.9.3 Question 41: Indicate the factors that have contributed to the adverse event.

Table 4.10 shows that multiple factors contributed to each adverse event that occurred, amongst others n=31 (75.6%) of the clinical manifestations were not responded to, n=28(68.3%) adverse events were due to poor monitoring and n=38(92.7%) failed to apply guidelines and protocols.

Table 4.10: Factors that contributed to the adverse event

	Frequency	Percentage
Clinical manifestations not responded to	31	75.6
Poor monitoring	28	68.3
Failing to apply guidelines/ protocols	38	92.7
Failing to give treatment as prescribed	32	78
Incorrect treatment	14	34.1
Accumulation of omissions	18	43.9
Accumulation of errors	7	17.1
System failures	6	14.6
Behavioural	9	22
Lack of supervision	5	12.2
Lack of training	19	46.3
Lack of knowledge	18	43.9

4.10 SUMMARY

The results have indicated that the clinical management of the patient is the predominant factor contributing to adverse events. Factors included are clinical manifestations not responded to and the failure to apply the necessary protocols and guidelines when providing care. As a result, the majority of the patients suffered an adverse event that is extreme in severity, according to the SAC Matrix and had their quality of life permanently affected.

4.11 CONCLUSION

In this chapter, the results obtained from the audit instrument were statistically analysed and described. The research question was adequately answered regarding the factors that contribute to malpractice litigation cases in nursing practice within the private healthcare sector of Gauteng.

In chapter five, the results will be discussed and concluded in accordance to the objectives of the study. Recommendations will be suggested based on the results and the limitations of the study will be discussed.

CHAPTER 5

DISCUSSIONS, CONCLUSIONS AND RECOMMENDATIONS

5.1 INTRODUCTION

The purpose of this study was to investigate factors that contribute to malpractice litigation cases within the private healthcare sector in Gauteng. In this chapter, conclusions based on the results analysed and described in the previous chapter are presented and recommendations for improvements within the healthcare services and among professional healthcare workers are proposed.

5.2 OBJECTIVES OF THE STUDY

5.2.1. To complete an audit of the nursing process

The nursing process consists of five phases, namely: assessment, diagnosis, planning implementation and evaluation, as explained in paragraph 2.8.3.2. Each of these phases is audited, to determine factors which contribute to malpractice litigation in nursing practice.

5.2.1.1 *Assessment*

It is critical to complete a full assessment of a patient that includes subjective and objective data which enables the health care professional to make an accurate diagnosis of the patient. An accurate diagnosis allows for accurate and appropriate management of the patient. An assessment not only emphasises physical data, but includes the biographic data of the patient which include the socioeconomic status of the patient i.e. occupation, income and education levels and social habits. In this study it was identified that 31.7% of the initial assessments were incomplete and 4.8% not documented. Amongst others, the smoking habit of the patient was not documented in 19.5% and the patient's alcohol usage in 24.4% of the records completed by the nursing profession upon admission. Documentation is critical as it provides continuity of a patient's care.

According to Weber and Kelley (2014:12) subjective data forms an integral part of the patient's healthcare history. The subjective data provides the nursing practitioner with information regarding the psychological, physiological as well as the sociological issues that could possibly be present.

5.2.1.2 *Diagnosis and care plans*

An accurate assessment as described in paragraph 5.2.1.1 will enable the healthcare practitioner to make an accurate diagnosis which may lead to the design of an accurate and appropriate patient care plan. The results of this study have shown that 9.8% of the care plans were incomplete and 21.9% were not documented.

5.2.1.3 *Implementation of care plans*

After the formulation of a care plan, it should be implemented to ensure that effective safe quality safe patient care is provided. However, this study showed that only 14.6% of the care plans were implemented. In patients who required a special care plan 19.5% were incomplete and 21.9% were not documented. The results further show that test results were incorrectly interpreted (22%) and not documented (19.5%) with 11.1% not reported to the doctor. Treatment was not given as required to patients in 48.8% of cases.

5.2.3.4 *Evaluation of the patient*

The study showed that 46.3% of the progress reports were incomplete and the progress reports were not documented in 4.8% of the nursing process documents. The continuous measuring and monitoring of a patient's condition is vital to evaluate the patient's response to the nursing interventions and progress towards the desired outcome (Doenges *et al.*, 2013:130). Progress reports found to be incomplete show a deficit in monitoring of the changes in the patient's condition and the evaluation of the efficiency of care. The progress report is the ongoing documentation of the patient's response to treatment and an absence thereof hinders the accurate reviewing of the desired outcome, as well as the patient's readiness for discharge.

The nursing practitioner manages the collaborative issues present in the patient's health by implementing both the medical practitioner and nurse-prescribed interventions. These collaborative efforts occur because the nurse assesses and treats the patient holistically (psychological, physical, social, spiritual and cultural), involving the assistance of other healthcare practitioners (Weber & Kelley., 2014:9). Results obtained in the study identified that 51.2% of the reports to the doctor were incomplete and 4.9% of the reports to the doctor were not documented. This study further identified that 75.6% of the patients' clinical manifestations were not responded to. Failure to report the changes in the condition of the

patient to the medical practitioner has a negative effect on the course of treatment, as the immediate intervention is delayed.

Interim reports reflect the action taken based on changes in the patient's condition and the intervention. This study shows that 51.2% of the interim reports were incomplete and 2.4% manifestations not reported. The lack of response to the clinical manifestations present can be interpreted as a breach in the quality of care provided, as the patients did not receive the optimal care they required for treatment to be effective. This could have had dire consequences, because of a lack of intervention to address or respond to a complication.

Discharge planning commences on admission of the patient to the healthcare setting and there are specific discharge criteria that patients and nursing practitioners must adhere to. These include adequate analgesia and pain control, stable vital signs, and no signs of active bleeding, obtaining a medical practitioner's order and patient education. This must be accurately documented upon the patient's departure, by the healthcare institution (Garber *et al.*, 2010:108). All patients required a discharge report, but the majority of the patients (78%) had no discharge reports documented and 22% were incomplete.

The National Health Act, 2003 (Act 61 of 2003) states that the healthcare provider must provide the patient with a comprehensive discharge report at the time of their discharge; this must include an accurate documentation of the nature of the service rendered, the prognosis of the patient, as well as the need for any follow-up treatment. The nursing practitioner is compelled legally to comply and apply these principles within the nursing discharge reports (McQuaid- Mason & Dada, 2011:100).

In paragraph 2.8.3.2 of chapter two, Regulation 786 outlines the nursing process which must include:

- Restore, support and promote the health status of the healthcare user
- Assist the healthcare user to maintain the basic activities necessary in their daily living
- Judgement is practised within a caring, therapeutic relationship
- Coordination and continuity of healthcare are maintained
- Continuous care and support are provided to the healthcare user through all stages of life, irrespective of their health state
- Provide and maintain a conducive and safe environment for healthcare

The researcher concludes that the objective about auditing the nursing process as found in the trial bundles was explored. Problematic areas were identified which may have contributed to the litigation of malpractice in nursing practice.

5.2.2 Categorising the adverse events according to principle type which involved nursing practitioners that have led to malpractice litigation.

The pressure to meet goals within the workplace may give rise to errors. The employees will make decisions based on the internal pressures they are experiencing and disregard the rules and procedures as required (Latino *et al.*, 2016:85).

The trial bundles reflected that multiple principle incident types were involved in one adverse event. All the trial bundles, (100%) reflected clinical management as the principle incident type in the adverse event. Paragraph 2.3 in chapter two explains that an error occurs when there is an unplanned deviation in treatment. These errors can be classified as it occurs in a particular context (Runciman & Watson, 2007:112).

According to the Swiss Cheese Model people within the healthcare sector, doctors and nurses, do not make many errors but when they do, these result in accidents. This is not the truth because they do make a large number of errors daily which are mostly inconsequential. The true errors are due to the universal conditions within the system, including inadequate equipment, poor scheduling of staff members and under-manning (Peltomaa, 2012:60). Results show that 22.0% were as a result of human behaviour, 17.1% organizational and 2.4% administration problems.

Section 30 of the Nursing Act (Act No.33 of 2005:25) sets out the scope of practice for the different categories of nurse within the nursing profession and state that individual nursing practitioners will be held accountable for their acts and omissions.

The majority of the trial bundles reflected that multiple categories of the nursing profession were involved in one adverse event. The professional nurse (70.7%) was shown to be the primary category involved in the adverse event, followed by the enrolled nurse (43.9%) and the enrolled nursing assistant (43.9%). The midwife was the primary category involved in 19.5% of the adverse events.

The nursing practice of South Africa is governed by the Nursing Act (Act No. 33 of 2005) and in utilizing the Act, the SANC is able to regulate the practice of nursing and the professional responsibilities of the nursing practitioner (Booyens, 2008:45). The acts and omissions as promulgated through the Nursing Act (Act No. 33 of 2005), enable the SANC to take disciplinary steps against a registered nurse practitioner who fails to maintain the health status of a healthcare user.

In conclusion, the dominating principle type category is the deficit in clinical management within the nursing practice that led to the adverse events. The professional nurse is the primary nursing category responsible for the adverse event that has led to malpractice litigation, including the enrolled nurse and enrolled nursing assistant to a lesser extent.

5.2.3 Identifying the factors contributing to the adverse events involving nursing practitioners that have led to malpractice litigation.

The study reflected that there were multiple factors that contributed to each adverse event that occurred. It was identified that in 75.6% of the clinical manifestations, 68.3% were not responded to as a result of poor monitoring of patients which contributed to the adverse event. The quality of medical and nursing care provided by the health practitioners of the Gauteng Department of Health is questioned due to the numerous instances of poor monitoring and negligent acts, as reported by patients. A financial compensation of 23 million rand was awarded to one mother due to prolonged labour and failure to perform a caesarean section at a South African hospital, leaving her now seven year-old son with permanent brain damage. The cause was due to negligent treatment by the relevant medical doctors and nurses involved (Sidimba, 2017:1).

Aggravating the situation further, the study revealed that 92.7% of the healthcare practitioners failed to apply guidelines and protocols. Uwaliraye et al. (2013:67) describe that the high rates of postpartum complications, as well as the patients' complaints regarding the quality of nursing care within the maternity unit were a reflection of the lack of adherence to policies that provide the necessary procedures to prevent life-threatening complications after birth.

James Reason as mentioned in paragraph 2.3, refers to latent organizational failures which may contribute to a near miss or an adverse event as shown in this study which identified that 14.6% system failures contributed to the adverse events. Illustrated further, Olifant (2017:1) explains that poor monitoring and negligence in medical care are not solely the cause of incompetent medical practitioners, as the death of 300 oncology patients in KwaZulu-Natal has been a result of the chronic shortage of specialists and the lack of specialized equipment required to provide quality treatment. Minister of Health, Aaron Motsoaledi, stated the procurement of services and human resources as the primary cause of the oncology crisis being faced in KwaZulu-Natal (Mthethwa, 2017:1).

Behavioural problems (22%) were identified as a contributing factor to the adverse events. A study conducted in private general hospitals in Gauteng, South Africa has found that the nursing participants have perceived themselves as being insensitive and not in full awareness to the emotional needs of their patients (van den Heever, Poggenpoel & Myburgh, 2013:6).

The study further showed that 12.2% was due to a lack of supervision and 46.3% due to a lack in training. Medical negligence experienced in the South African private and public sectors was caused by the nursing staff displaying characteristics of poor training and negative attitudes. It was identified by a medical negligence attorney who reported that under-qualified

nurses are working in intensive care units in private hospitals and specialized care is not up to standard (Child, 2014:1).

The researcher concludes that multiple factors contribute to an adverse event as shown in this study. The predominant factor being the failure to apply the necessary guidelines and protocols.

5.2.4 Identifying the other members of the multi-disciplinary health team that played a role in the adverse event that has resulted in malpractice litigation

The nursing profession was responsible for 41.5% of the adverse events while 29.3% included both medical and nursing profession. Daud-Gallioti et al., (2012:12) conclude that nurse staffing is considered as a possible factor leading to health associated infections within an intensive care unit, as non-compliance to the nurses' patient care plans was identified.

In conclusion, the objective was explored and has identified that both the medical and nursing professions are involved in adverse events.

5.2.5 Assessing the severity of the adverse event that has led to malpractice litigation

The Safety Assessment Code (SAC) was applied in assessing the severity of each adverse event as described in paragraph 2.5 (SA Health Risk Management Framework, nd).

This study revealed that most adverse events were severe (46.3%), major (36.6%), moderate (14.6%) and minor (2.4%).

Due to the severity of the adverse events (48.8%) of the plaintiffs required additional surgery, 7.3% of the plaintiffs died due to the adverse event and the majority 92.7% of the plaintiffs' quality of life was negatively affected.

In conclusion, this objective was explored and the adverse events were successfully classified according to its severity level. According to these results most plaintiffs suffered a severe adverse event.

5.3 RECOMMENDATIONS

Based on the research study results, the researcher suggests the following strategies to enhance the clinical practices for the reduction of the prevalence of adverse events leading to malpractice litigation.

5.3.1 Training courses in clinical management for continuous professional development

Continuous Professional Development (CPD) means to advance healthcare practitioners within their professional career. It is expected that all practitioners will continue to develop within their working lives, thus evolving from a student practitioner, to becoming specialised in the field and ultimately advanced within the health profession (Jasper, 2013:2).

The professional development programme is to ensure the continuous maintenance of competency in the theoretical as well as practical components needed within the healthcare setting. This include short courses within the speciality area that the professional nurse practices, appealing to the individuality of the care provided within the particular specialised health setting. This ensures the nursing practitioner on duty is knowledgeable and skilled in their area of employment. The study reveals that 29 adverse events had the professional nurse as the primary category involved in the adverse event.

In order to execute delegated tasks according to a systematic sequence, the adequate skills and level of competence is required by the nursing practitioner performing the task. When the nurse is not competent and confident when interacting with the patient and incompetent when executing the tasks required, an adverse event is likely to occur.

5.3.2 Supervision

The results of the study show that five of the adverse events were due to a lack of supervision within the clinical area. It is imperative that there is always a senior nursing practitioner present to guide a junior practitioner. This will allow the senior nursing practitioner to identify the current level of competency with which duties are executed. It is within this context that hands on training applicable to the shortcoming can occur and safe quality patient care can be ensured.

This will also instil confidence within the junior nursing practitioners as they are able to verbalize areas where they are unsure and require guidance.

5.3.3 Reviewing of policies and procedures

Adherence to the guidelines set out in the health institution's policies and procedures has been an issue. As the results, reflect this caused thirty-eight adverse events. James Reason explains in the Swiss Cheese Model that these contribute to latent failures as the nursing practitioner is not knowledgeable about the proper manner of execution according to the set guidelines, leaving the opportunity for the adverse event to occur.

Health institutions should ensure that all policies and procedures are read and understood by the nursing personnel, as it applies to their specialty area.

5.3.4 Procurement and budgeting

The results of the study have shown that six adverse events were as a result of system failures within the organization, including the lack of equipment and resources needed to provide safe quality nursing care. If the nursing practitioners are not equipped with the resources necessary to effectively execute their duties, this negatively impacts patient safety. Health institutions must ensure that the procurement and budgeting is in line with the needs of the clinical area. Latent failures give rise to adverse events when nursing practitioners function at a deficit within their clinical environment.

5.3.5 Address the shortage of nursing practitioners

It is not possible to deliver quality nursing care when the human resources are not available to attend to the holistic needs of the patient. Health institutions should address this factor with urgency and ensure that there are enough skilled nursing practitioners within the clinical area to execute their duties. James Reason explains the true errors are due to the universal conditions within the system, including poor scheduling of staff members and under-manning (Peltomaa, 2012:60).

5.3.6 Addressing behavioural problems and attitudes within the workplace

Along with adverse events and the nursing practitioners, comes the demeanour and attitude of the nurses providing the care to the patient. The results reflect nine adverse events as a result of behavioural issues.

Boysen (2013:400) describes a just culture in healthcare as balancing the need for open and honest reporting system within a quality learning environment. The health organization ultimately has a responsibility towards the patients and a shift from errors towards management of behavioural choices amongst healthcare providers ensures a just culture in healthcare. Introduce an audit review of adverse events in the health establishment for staff. This could be offered as an in-service training opportunity where the nursing personnel can be made aware of the adverse events as well as the near misses within the organization and how these gaps is negatively affecting the quality and safety of patient care.

5.3.7 Adverse event reporting

Health care institutions must analyse this information with urgency and provide feedback to the person who reported the incident in the first place- as well as the other parties involved, and create a learning opportunity. Thus creating a platform into taking action for improvement.

If organizations are to improve the culture of reporting incidents amongst staff members- a number of barriers must be overcome namely: the clinical staff becoming anxious about being blamed as well as the time it takes to submit an official report and what management will do with the information once they have it. Most importantly, to reassure staff members that the process is worthwhile and that it can make a difference to practice (Woodward *et al.*, 2004:87).

5.4 LIMITATIONS

Several malpractice law firms were contacted on numerous occasions telephonically and via electronic mail, in order to participate in the study. Due to the sensitivity of the data, they refused the researcher access to their documents in fear of a breach in the plaintiff's confidentiality. Due to the limited access granted, a total of forty-one trial bundles were audited for this study. The law firms who granted the researcher permission to access their trial bundles would like to remain anonymous, to ensure there is no link between the name of the firm and the data reflected. Another limitation was the law firms refusing the researcher access to the quantum of each court case.

5.5 CONCLUSION

The research question of “What are the factors that contribute to malpractice litigation in nursing practice within the private healthcare sector of Gauteng?” has been addressed as the factors contributing to adverse events within nursing practice have been identified and thoroughly explored by linking with the objectives of the study. It was highlighted that the clinical management of the patient is a major problem, as well as the adherence to the policies and protocols under which the nursing duties should be performed. The effects of adverse events leading to medical malpractice litigation are on the rise and the healthcare system is being negatively affected. The pay-out for negligence is costing the taxpayers of South Africa billions of rand every year. This is a crisis that needs immediate attention and effective intervention.

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Appendix 1: Instrumentation tool**AUDIT INSTRUMENT****TITLE: INVESTIGATION INTO THE FACTORS THAT CONTRIBUTE TO MALPRACTICE LITIGATION IN NURSING PRACTICE WITHIN THE PRIVATE HEALTHCARE SECTOR OF GAUTENG.****No: _____ (Office use only)****Audit the malpractice litigation case and complete the following sections.****The audit instrument****SECTION A: THE LITIGATION (Questions 1-4)****1 How was the court case presented?**

1	In the High Court	
2	Settled out of Court	

2 If presented in court indicate which High Court.

1	North Gauteng High Court (Pretoria)	
2	South Gauteng High Court (Johannesburg)	

3 If settled out of court indicate the amount for which the case was settled

4 If presented in court indicate the outcome of the judgement, if specifically the quantum to be paid

SECTION B: DEMOGRAPHIC DATA OF THE PATIENT (Questions 5-13)**5 Age:****6 Gender**

1	Female	
2	Male	

7 Marital status

1	Single	
---	--------	--

2	Married	
3	Partner	
4	Widow	
5	Widower	
6	Divorced	

8 Dependents

1	None	
2	One	
3	Two	
4	Three	
5	>Three	
6	Not documented	

9 Any disability on admission

1	Yes	
2	No	

10 Indicate whether the patient had any of the following social habits

	Item	Yes	No	Not documented	N/A if a baby/child
1	Smoking				
2	Using unsolicited drugs				
3	Alcohol				

11 Any underlying medical condition on admission e.g. hypertension

1	Yes	
2	No	

12 Choose one of the following: Employment at the time of admission to the hospital

1	Employed	
2	Self-employed	
3	Not employed	
4	Pensioner	
5	N/A e.g. child	

13 Choose one of the following: Type of employment

1	Professional e.g. teacher, nurse, pilot, doctor	
2	Technical	
3	Businessman	
4	Administrative	
5	Tradesman	
6	Labourer / Unskilled	
7	Other	
8	Not documented	

SECTION C: HOSPITALIZATION (Questions 14-32)**14 Indicate whether the nursing ward notes are available to audit**

1	Yes	
2	No	

15 Indicate the reason for admission

1	Elective surgery	
2	Planned treatment	
3	Emergency	
4	Ill /Sick requires medical care	
5	Other	

16 Indicate the type of discipline (s) to which the patient was admitted before the adverse event

1	Cardiology	
2	Dermatology	
3	Gynaecology	
4	Medical	
5	Midwifery / Obstetrics	
6	Neonatology	
7	Nephrology	
8	Neurosurgery	
9	Neurology	
10	Orthopaedics	
11	Ophthalmology	

12	Paediatrics	
13	Psychiatry	
14	Trauma	
15	Urology	
16	Gen Surgery	
17	Cardiac surgery	
18	Other (<i>specify</i>)	

17 Indicate the type of ward / unit to which the patient was admitted before the adverse event

1	Emergency / Casualty	
2	General ward	
3	Paediatrics	
4	ICU	
5	Antenatal ward	
6	Labour	
7	Neonatology	

18 Indicate whether the initial assessment including the fetus where applicable was:

1	Complete	
2	Incomplete	
3	Not documented	

19 Indicate the status of the care plan of the patient: (Includes all types of patients)

1	Complete	
2	Incomplete	
3	No care plan	

20 Indicate whether the care plan was implemented?

1	Yes	
2	No	
3	N/A	

21 Indicate whether special care plans were required e.g. for a diabetic patient, patient in labour.

1	Yes	
2	No	

22 Indicate the status of the special care plan of the patient:

1	Complete	
2	Incomplete	
3	No care plan	
4	N/A	

23 If yes as indicated in question 23 indicate whether the special care plan was implemented.

1	Yes	
2	No	
3	N/A	

24 Indicate whether any of the following vital signs were monitored. (More than one response)

	Item	Complete	Incomplete	Not documented	N/A
A	Blood pressure				
B	Pulse				
C	Foot pulses				
D	Fetal				
E	Respiration				
F	Temperature				
G	Intake and output				
H	Weight				
I	Neuro observations				
J	Post-spinal surgery				
K	Mental status				
L	Continuous ECG monitoring				
M	Continuous oxygen saturation monitoring				
N	Other				

25 Indicate whether the following diagnostic tests were done pre-adverse event where applicable

	Item	Yes	No	N/A
A	Haemoglucotest			

B	Haemoglobin			
C	Urine tests			
D	Urea and electrolytes			
E	Blood gasses			
F	Full blood count			
G	Liver functions			
H	Other			

26 Were the results of the tests interpreted?

1	Correctly interpreted by the Professional Nurse	
2	Incorrectly interpreted	
3	Not interpreted	

27 Were the results reported to the doctor?

1	Yes	
2	No	
3	N/A	

28 If any diagnostic tests were done indicate whether action was taken based on the results

1	Yes	
2	No	
3	N/A	

29 Where applicable indicate whether the preoperative assessment FOR SURGERY was

1	Complete	
2	Incomplete	
3	Not documented	

30 Indicate whether the treatment / technique / management as prescribed was given

1	Yes	
2	No	

31 Do the patient's progress reports reflect the following about the patient? (More than one response)

	Item	Complete	Incomplete	Not documented	N/A
1	Initial report				
2	Progress				
3	Interim report				
4	Reports to the doctor				
5	Discharge report				

32 If the patient was discharged indicate whether specific patient education was given

1	Yes	
2	No	
3	N/A	

SECTION D: OPERATING ROOM (Questions 33)

33 Indicate where applicable whether the following protocols in the operating room were adhered to:

	Item	Yes	No	N/A	Not documented
A	Counting swabs				
B	Infection control				
C	Managing instruments				
D	Managing specimens				
E	Use of the diathermia				
F	"Surgical pause" or "Time out"				
G	Other				

SECTION E: ADVERSE EVENT(s) (Questions 34-38)

34 Indicate the environment where the adverse event(s) occurred

	Item	Yes	No
A	General ward		
B	ICU		
C	Operating room theatre		
D	Paediatric ward		
E	Neonatology unit		
F	Casualty / Trauma		
G	Labour		
H	Psych		

1	Other <i>Specify</i>		
---	----------------------	--	--

35 Describe the adverse event(s)

36 Indicate the patient outcome(s) as a result of the adverse event. (Could be more than one response)

	Item	Yes	No
1	Additional surgery		
2	Death		
3	Disabled		
4	Increased hospital stay		
5	Quality of life affected		

37 Healthcare profession(s) or non-healthcare professional responsible for adverse event

1	Nursing	
2	Medical	
3	Both nursing and medical	
4	Non-healthcare professional	
5	Both nursing and non-healthcare professional	
6	Other	

38 If nursing or both nursing and medical were chosen in question 39 indicate the category (s) of nurses involved in the adverse event

A	Professional nurse	
B	Enrolled nurse	
C	Enrolled nursing assistant	
D	Midwife	

SECTION F: PRINCIPLE INCIDENT TYPE, SEVERITY OF ADVERSE EVENT AND FACTORS CONTRIBUTING TO THE ADVERSE EVENT (Questions 39-41)

39 Indicate the adverse event by Principle Incident type

1	Admin	
2	Clinical management	
3	Human behavior problems	
4	Organizational	
5	Other	

40 Indicate the severity of the adverse event according to the Safety Assessment Code Matrix (SAC)

1	Extreme	
2	Major	
3	Moderate	
4	Minor	
5	Insignificant	

41 Indicate which of the following FACTORS contributed to the adverse event. In this question there could be more than one answer (question 41)

A	Clinical manifestations not responded to	
B	Poor monitoring	
C	Failing to apply guidelines/ protocols	
D	Failing to give treatment as required	
E	Incorrect treatment	
F	Accumulation of omissions	
G	Accumulation of errors	
H	System failures	
I	Behavioural e.g. attitude	
J	Lack of Supervision	
K	Lack of training	
L	Lack of knowledge	
M	Other <i>Specify</i>	

End adapted from the pilot study for this sub study.

Amy Williams

Appendix 2: Ethical approval



Approved with Stipulations

Response to Modifications-
(New Application)

31-Jan-2017

Williams, Amy A

Ethics Reference#: S16/10/222

Title: Investigation into the factors that contribute to malpractice litigation in nursing practice within the private healthcare sector of Gauteng.

Dear Miss Amy Williams,

The Response to Modifications (*New Application*) received on 20-Jan-2017, was reviewed by members of Health Research Ethics Committee 1 via Expedited review procedures on 27-Jan-2017.

Please note the following information about your approved research protocol: Protocol

Approval Period: 31-Jan-2017 -30-Jan-2018

The Stipulations of your ethics approval are as follows:

Before this study commences, signed consent letters from the legal firms are required in which permission is granted to access the cases/case material.

Please remember to use your protocol number (S16/10/222) on any documents or correspondence with the HREC concerning your research protocol.

Please note that the HREC has the prerogative and authority to ask further questions, seek additional information, require further modifications, or monitor the conduct of your research and the consent process.

After Ethical Review:

Please note a template of the progress report is obtainable on www.sun.ac.za/rds and should be submitted to the Committee before the year has expired. The Committee will then consider the continuation of the project for a further year (if necessary). Annually a number of projects may be selected randomly for an external audit.

Translation of the consent document to the language applicable to the study participants should be submitted.

Federal Wide Assurance Number: 00001372

Institutional Review Board (IRB) Number: IRB0005239

The Health Research Ethics Committee complies with the SA National Health Act No.61 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 Part 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes 2004 (Department of Health).

Provincial and City of Cape Town Approval

Please note that for research at a primary or secondary healthcare facility permission must still be obtained from the relevant authorities (Western Cape Department of Health and/or City Health) to conduct the research as stated in the protocol. Contact persons are Ms Claudette Abrahams at Western Cape Department of Health (healthres@pgwc.gov.za

Tel: +27 214839907) and Dr Helene Visser at City Health (Helene.Visser@capetown.gov.za Tel:+27 21 400 3981). Research that will be conducted at any tertiary academic institution requires approval from the relevant hospital manager. Ethics approval is required BEFORE approval can be obtained from these health authorities.

We wish you the best as you conduct your research.

For standard HREC forms and documents please visit: www.sun.ac.za/rds

If you have any questions or need further assistance, please contact the HREC office at.

Included Documents:

Fast Track letter.pdf

HREC Application A Williams.pdf

A Williams Submission

Audit Instrument.docx

20170123 MOD Cover

letter

A Williams Submission

Curriculum Vitae.docx

20170123 MOD HREC

Modifications Required.pdf

A Williams Submission

General Checklist.docx

A Williams Submission Investigators Declaration.pdf

Abbreviated CV Oct 2016 PROF

ETHELWYNN L STELLENBERG.

pdf Waiver letter.pdf

20170123 MOD Protocol

A Williams Submission

Synopsis.docx

Investigators declaration

Supervisor.pdf

A Williams Submission Research Proposal.docx

Sincerely,

Franklin

Weber

HREC Coordinator

Health Research Ethics Committee I

Appendix 3: Language editing certificate



Lona's Language Services

English/Afrikaans
Afrikaans/English

3 Beroma Crescent Beroma Bellville
Tel 0219514257
Cell 0782648484
Email illona@toptutoring.co.za

* Translations * Editing * Proofreading
* Transcription of Historical Docs
* Transcription of Qualitative Research
* Preparation of Website Articles

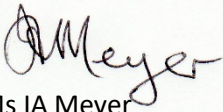
TO WHOM IT MAY CONCERN

This letter serves to confirm that the undersigned

ILLONA ALTHAEA MEYER

has proofread and edited the document contained herein for language correctness.

Signed



Ms IA Meyer

6 December 2017

FOR: AMY WILLIAMS

TITLE: Investigation into the factors that contribute to malpractice litigation in nursing practice within the private healthcare sector of Gauteng.